Bartësi Privat i Arsimit të Lartë
Private Bearer of Higher Education

KOLEGJI I SHKENCAVE MJEKËSORE "REZONANCA"
COLLEGE OF MEDICAL SCIENCES "REZONANCA"
P r i s h t i n ë

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CURRICULUM

MASTER OF SCIENCE IN PHARMACY

2019/2020

MASTER OF SCIENCE IN PHARMACY STUDY PROGRAM

1. Information about study programme

Name of the Institution:	COLLEGE OF MEDICAL SCIENCES "REZONANCA"
Name of the study program:	Master of Science in Pharmacy
Person in charge for the study programme:	Dr.sc. Ardian Rugova
Level of qualification according to NQF:	Level VII
Academic degree or the name of Diploma:	Master of Science in Pharmacy
ECTS:	120
Erasmus Subject Area Codes (ESAC)	12.5
Form of studies:	Full Time
Minimum duration of studies:	2 years (4 semesters)
Tuition fees	

2. Rationale of the labor market program

According to Kosovo law for personal community pharmacy opening required master's level studies.
Also, the program represents the continuation of the study in the second round according to the Bologna process.

3. International comparability of program

The program is in accordance with Directive 2005/36/EC of the European Committee for the medical professions.

As such the program is comparable to programs of European Union countries, especially with Master program of Copenhagen University, Denmarc.

The program is designed in accordance with the Bologna Process secound cycle higher vocational education, according to the NQF level 7 / (EQF).

4. Target Group

To qualify for admission to the programme, applicants must have:

1. Completed a bachelor's degree in the pharmacy program

2. Accumulated at least 180 ECTS credits (3 full academic years)
3. Applicants from non EU/EEA countries who speak or write Albanian/English as a second language must have passed the Albanian Language test with a score minimum of 6.0 in the paper based test. Tests must be submitted to the Faculty of Medical Sciences directly from the test centre of Albanological Institute.

The Faculty of Medical Sciences reserves the right to request further information from institutionës] of higher education at which you have studied earlier.

5. Orientation program of study leading principles of the institution (mission)

This graduate entry master course enables science graduates to become registered pharmacists. It will provide the students with a comprehensive theoretical base, including chemical, biological, physiological, pharmaceutical and pharmacotherapeutics studies.
During the first semester students will be introduced to important concepts in Drug Discovery and Development, Advanced Synthetic Organic Chemistry and Pharmaceutics and Drug Development
The rest of first year will focus on Pharmacology from Physiology to Therapy, Principles and Practice of Bioanalysis and In-vitro Techniques in Biochemistry and Pharmacology

In second year the students will focus on pharmacotherapy and develop research skills in Social and Clinical Pharmacy. Students also complete a hospital placement to cement their practical skills.
Graduates are both highly employable and sought after. As a graduate, you may seek a career in health care working in the fields of community, hospital or consult pharmacy.

6. The purpose and profile of the study program

Graduates are required to complete a preregistration training period and register as a pharmacist before being able to commence practice in most areas of the profession. Graduates are able to register to practice in all territories in Kosova.

Graduates are both highly employable and sought after. As a graduate, you may seek a career in health care working in the fields of community, hospital or consult pharmacy.

7. Learning outcomes

Throughout this course students use high quality laboratories and facilities designed to enhance teaching and provide students with essential practical skills. The school laboratories include a analytical lab, a manufacturing laboratory in pharmaceutical

industry, an asepsis suite and laboratories for microbiological, chemical and pharmacological investigations.
The role of the pharmacist within community pharmacy has expanded to include assisting patients with the management of their chronic diseases, such as obesity, asthma and diabetes. In the future, pharmacists in the primary care setting are going to become increasingly involved in the care of patients through multidisciplinary teams. The setting of practice of pharmacy will expand from the community pharmacist to include medical clinics and the patient's home. Within hospitals, pharmacists provide a diverse range of services from drug distribution and dispensing, provision of drug information and education, through to ward-based clinical pharmacy services where they participate in patient care as part of a team. Hospital pharmacists may also engage in quality assurance programs and clinical research.

Consultant pharmacists provide medication management review services. They work in collaboration with patients and their doctors to ensure the patient achieves the best outcomes from their drug therapy. Such pharmacists work in aged care facilities and/or patients' homes.

Graduates may also develop a career in the pharmaceutical industry which employs pharmacists in a number of areas including research roles in the development of medicines, production of pharmaceuticals, quality assurance, regulatory services, marketing and drug information.

Graduates may also work for the State or Federal Government in regulatory and policy roles.

8. The relationship between theoretical and practical study

Theoretical and practical ratio is 1:3.5 (366 theoretical contact hours and 1290 practical contact hours).

9. Calculation of ECTS

Calculation of ECTS is made according to the Guidelines for calculation of ECTS, which are taken into consideration all commitments student teaching to fulfill the obligations of each subject.
1 ECTS is the equivalent of 25 classes, respectively year is 1500 hours, or 60 ECTS.

10. Practical work – internship

The setting of practice of pharmacy will expand from the community pharmacist to include medical clinics and the patient's home. Within hospitals, pharmacists provide a diverse range of services from drug distribution and dispensing, provision of drug information and education, through to ward-based clinical pharmacy services where they participate in patient care as part of a team. Hospital pharmacists may also engage in quality assurance programs and clinical research.

Consultant pharmacists provide medication management review services. They work in collaboration with patients and their doctors to ensure the patient achieves

the best outcomes from their drug therapy. Such pharmacists work in aged care facilities and/or patients' homes.

Graduates may also develop a career in the pharmaceutical industry which employs pharmacists in a number of areas including research roles in the development of medicines, production of pharmaceuticals, quality assurance, regulatory services, marketing and drug information.

Participating Institutions:

1. Pharmaceutical Industry Manufacturer "TREPHARM", Sllatinë e Madhe, Fushë Kosovë. (Contract date 28.05.2013)

2. Pharmaceutical Industry Manufacturer "FARMAKOS New Co.", Prizren, Kosova. (Contract signed on 23.05.2010)

3. Pharmacies "Leka Med", Prishtina, Kosova – community pharmacy (Contract signed on 23.05.2010)

4. National Institute for Public Health, Prishtinë, Kosovë – public health institution of the country (Contract no.292, date 18.04.2011)

5. Academy of Science of Albania, Tirana, Albania– The highest scientific institution of the country (Contract no.40, date 03.03.2009)

6. Faculty of Medical Health Studies, Sarajevo, Bosna and Hercegovina, Department of Pharmacy (Contract no.21/012, date 27.01.2012)

7. Consortium AGROVET–Faculty of Medical Scences "Rezonanca" (No.73/13, date 28.01.2013)

PLAN OF STUDY

Year - 1

No.	Course	Code	Sem.	L	P	Proj.	RW	Contact hours	Indep. Study	Total	ECTS
1	Drug Discovery and Development	MSPh-CC-1011	1	24	18	75	0	117	133	250	10.0
2	Advanced Synthetic Organic Chemistry	MSPh-CC-1012	1	24	45	0	24	93	82	175	7.0
3	Pharmaceutics and Drug Development	MSPh-CC-1013	1	24	20	45	30	119	131	250	10.0
4	Elective course	MSPh-EC-1014	1	20	20	0	0	40	35	75	3.0
	Subtotal			92	103	120	54	369	381	750	30.0
5	Principles of Pharmacology	MSPh-CC-1021	2	40	6	20	20	86	164	250	10.0
6	Principles and Practice of Bioanalysis	MSPh-CC-1022	2	30	55	0	0	85	165	250	10.0
7	In-vitro Techniques in Biochemistry and Pharmacology	MSPh-CC-1023	2	15	45	0	27	87	88	175	7.0
8	Elective course	MSPh-EC-1024	2	20	20	0	0	40	35	75	3.0
	Subtotal			105	126	20	47	298	452	750	30.0
	TOTAL		No	197	229	140	101	667	833	1500	60.0

L=Lecture; P=Practice; Proj.=Project; RW=Report writing

Year - 2

No.	Course	Code	Sem.	L	P	Proj.	RW	Contact hours	Indep. Study	Total	ECTS
9	Pharmacology: From Physiology to Therapy	MSPh-CC-2031	3	60	5	35	0	100	100	200	8.0
10	Pharmacokinetics and Pharmacodynamics	MSPh-CC-2032	3	50	0	0	30	80	70	150	6.0
11	Advanced Manufacturing of Pharmaceuticals	MSPh-CC-2033	3	30	14	36	0	80	70	150	6.0
12	Research Methods in Pharmacy	MSPh-CC-2034	3	40	30	35	20	125	125	250	10.0
	Subtotal			180	49	106	50	385	365	750	30.0
13	Elective course	MSPh-EC-2041	4	20	20	0	0	40	35	75	3.0
14	Elective course	MSPh-EC-2042	4	20	20	0	0	40	35	75	3.0
15	Master Thesis	MSPh-CC-2043	4	0	0	600	0	600	0	600	24.0
	Subtotal			40	40	600	0	680	70	750	30.0
	TOTAL		No.	220	89	706	0	1065	435	1500	60.0

SYLLABUSES

Name of the course	Drug Discovery and Development	**1**
Year of study	I	
Semester	1.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	24
	Practical work:	18
	Project work:	75
	Report writing	0
Total contact hours:	117	
Independent study:	133	
Total hours:	250	
ECTS:	10.0	

Objektivat e kursit/Course Objectives

Objektivat e kursit/Course Objectives:

To introduce students to the various phases involved in drug discovery and development, as well as to give them an overview and a solid understanding of the dynamics and interdisciplinary nature of the development process. The course is built around a project that the students work on for the entire course duration. Information needed for the project is found in the course materials.

Përmbajtja e kursit/Course Content

In order to give students insight into and an overview of the drug discovery and development process in a pharmaceutical company, lectures and class lessons are given on the following topics:

- Target identification, evaluation and identification lead structures
- Medicinal chemistry: Lead optimisation and synthesis
- Non-clinical safety assessment
- Pharmacology
- Pre-formulation
- Pharmaceutical formulation
- Clinical trials
- Regulatory affairs
- Production
- Marketing

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ **Knowledge and Understanding:**

	1	At the end of the course, students should have a solid overview of the academic disciplines, interdisciplinary nature and dynamics of drug development. More specifically, the student should be able to demonstrate: - Understanding of the basic academic disciplines involved in drug discovery and development
	2	Understanding and ability to use the basic technical terms used in drug discovery and development
	3	The ability to identify critical parameters in industrial drug development
	4	Understanding of his or her own professional role in the drug development process seen in relation to his or her own expertise and academic profile
	5	The ability to define key issues associated with a drug development process
	6	
Shkathtësitë intelektuale**/** Intellectual skills		
	1	Self-directed learning
	2	Applying theory to practice
	3	Use of scientific literature, library, presentation and scientific skills
Shkathtësitë praktike profesionale/ Professional practical skills		
	1	
	2	
	3	
	4	
Shkathtësitë për transferimin e njohurive/ Transferable skills		
	1	Communication skills, including listening skills
	2	Reflective practices
	3	Teaching, presentation skills
Qëndrimet dhe sjelljet/ **Attitudes and behavior**		
	1	
	2	
	3	
	4	
	5	
PËRMBLEDHJA E KURSIT/ORARI (javor) COURSE OUTLINE/SCHEDULE (Weekly)		
		LECTURES
	1	INTRODUCTION TO DRUG DESIGN AND DEVELOPMENT
	2	DRUG TARGETS
	3	ENZYMES (CATALYTIC RECEPTORS) AS DRUG TARGETS
	4	ENZYME INHIBITION AND INACTIVATION

	5	Mid-Term Exam – Test 1
	6	RECEPTORS AS DRUG TARGETS
	7	DNA AND DNA-INTERACTIVE AGENTS
	8	RNA AS A DRUG TARGET
	9	DRUG DEVELOPMENT
	10	Mid-Term Exam – Test 2
	11	*COMPUTER-AIDED DRUG DESIGN*
	12	DRUG DESIGN BASED ON THE PHARMACOKINETIC MODIFICATIONS
	13	PRE-CLINICAL AND CLINICAL TESTING
	14	BIOPHARMACEUTICALS. CLINICAL IMAGING IN DRUG DEVELOPMENT
	15	Mid-Term Exam – Test 3
		PRACTICE
	1	Drug Discovery as a Process Drug Discovery without a Lead: Penicillins, Benzodiazepines Lead Discovery: Random screening, Nonrandom screening, Drug metabolism studies, Clinical observations, Rational approaches to Lead Discovery
	2	Drug target Identification, Validation and Screening.
	3	Targeting human enzymes Targeting enzymes selective of invading organisms Enzymes as Catalysts. Mechanism of enzyme Catalysis. Coenzyme catalysis. Enzyme Therapy
	4	Peptidomimetics, NRTIs, NNRTIs, NtRTIs, protease inhibitors, Nucleotide triphosphate inhibitors, chain elongation inhibitors, DNA polimerase Inhibitors
	5	
	6	Membrane transporters as drug targets Voltage-gated ion channels G-protein-coupled receptors Receptors with intrinsic enzyme activity Nuclear receptors
	7	DNA intercalators: Intercalation and topoisomerase induced DNA damage. DNA Alkylators DNA Strand breakers
	8	TARGETING RIBOSOMAL RNA: AMINOGLYCOSIDES, RNA-BASED THERAPEUTICS: Antisense therapies (mipomersen,oblimersen), RNA interference (RNAi) therapeutics, nucleic acid or peptide aptamers (Pegaptanib), anti-microRNA (anti-miR) therapeutics
	9	The nature of Drug Development Components of the drug development The interface between the discovery and the development Identification of Pharmacophore; Structure Activity Relationships (SAR); Structure Modifications to increase potency and Therapeutic Index, Analog Design, Bioisosterism; Quantitative Structure Activity Relationships (QSAR); 3D-QSAR

	10	
	11	Design of drugs to treat hypertension, RAS; Inhibitor design for ACE; Design of renin inhibitors; design of drugs for the treatment of AIDS Molecular Modelling Molecular Modelling Visualization
	12	Drug Delivery Bioavailability, Prodrugs Principles of drug delivery systems Pharmaceutical development Preformulation studies Routes of administration and dosage forms Formulation
	13	LEGAL ASPECTS OF PRODUCT PROTECTION DRUG NOMENCLATURE REGULATORY AFFAIRS Brief history of Pharmaceutical Regulation. International Harmonization Roles and Responsibilities of regulatory authority and company The drug development process: Regulatory procedures and administrative rules MARKETING THE DRUG
	14	Recombinant DNA technology Currently available classes of biopharmaceutics Gene therapy
	15	▪ Mid-Term Exam – Test 3

Resurset/Resources

Materiali i nevojshëm për kurs/Librat

Required Course Material(s)/Reading(s)/Text Book(s)

- Drug Discovery and Development; Technology in Transition. HP Rang. Elsevier Ltd 1st edition 2006.
- Pharmacology in Drug Discovery. T. P. Kenakin. Elsevier, 1st Edition 2012.
- An introduction to medicinal chemistry. G. L. Patrick. 5th Edition Oxford UK, Oxford University Press, 2013.

Materiali i nevojshëm për kurs/Librat tjera për lexim

Recommended Course Material(s)/Reading(s)/Other

- Textbook of Drug Design. Krogsgaard-Larsen, Liljefors and Madsen (Editors), Taylor and Francis, London UK, 2002.
- Drug Discovery Handbook S.C. Gad (Editor) Wiley-Interscience Hoboken USA, 2005.

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	**NUMRI/ NUMBER**	**Përqindja në gradim/ Percentage of Grade**
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5

Laborato/Laboratori/ry	1	10
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëspisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	1	20
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	3*5	15
Vlerësimi final/Final	1	45
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	**NUMRI NUMBER**	**Kohëzgjatja (orë) Duration (Hours)**	**Ngarkesa Totale Total WorkLoad**
Orë mësimi/ Course Hours	15	1.6	24
Laborator/ Laboratory	15	1.2	18
Provim praktik/ Practical Exam	0	0	
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	
Puna në Terren/ Field Work	0	0	
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	15	8.9	133
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop	0	0	
Projekt/ Project	15	5	75
Detyra të shtëpisë/ Homework Assignments	0	0	
Kuize/ Quizzes	0	0	
Vlerësim në Mesterm/ Midterm(s)	3	0.5	1.5
Vlerësim Final/ Final EXAM	1	1	1
Ngarkesa Totale/ Total WorkLoad			**252.5**
Ngarkesa Totale/25 Total Workload/ 25			**10.1**
ECTS			**10.0**

Name of the course	Advanced Synthetic Organic Chemistry	**2**
Year of study	I	
Semester	1.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	24
	Practical work:	45
	Project work:	0
	Report writing	24
Total contact hours:	93	
Independent study:	82	
Total hours:	175	
ECTS:	7.0	

Objektivat e kursit/Course Objectives

To build the student's knowledge of advanced synthetic organic chemistry as well as to illustrate different methods, techniques, and equipment, learning the combination of literature and theoritical knowledge with laboratory work.

Përmbajtja e kursit/Course Content

Modern trends in organic synthesis. Types of advanced organic reactions and their mechanisms.

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

1 Knowledge of modern approaches in organic chemistry.

2 Knowledge of mechanisms of organic reactions.

4 Understanding the influence of different parameters on the reaction course.

Shkathtësitë intelektuale/ Intellectual skills

1 Independent study.

2 Applying theory to practice.

3 The use of scientific literature, libraries, scientific databases on the internet, presentation and scientific skills.

Shkathtësitë praktike profesionale/ Professional practical skills

1 Ability to design, interpret, and analyze appropriate experiments required for performing an organic reaction mechanism.

2 Synthesizes isolates and cleans organic compounds as well as critically evaluates results thus obtained.

Shkathtësitë për transferimin e njohurive/ Transferable skills

1 Communication skills including listening skills.

2 Reflective practices.

3 Learning, presentation skills.

Qëndrimet dhe sjelljet/ Attitudes and behaviour

1 Ensuring confidentiality.

2 Sensitivity to individual differences during communication.

	3	Appropriate attitudes to self-motivated learning and scientific thinking during the career.
	PËRMBLEDHJA E KURSIT/ORARI (javor) COURSE OUTLINE/SCHEDULE (Weekly)	
	Java/Week	Tema/Topics – LEKSIONE/LECTURES
	1	▪ Mechanism of a chemical reaction, definitions, elementary and stepwise reactions, bond making and bond breaking, resonance, inductive and steric effects. Kinetics and thermodynamics of organic reactions; equilibrium and rate constants, energy reaction diagrams, transition states, reaction intermediates.
	2	▪ Nucleophilic aliphatic substitution, mechanism, and stereochemistry. Relative reactivity of substitution, competitive reactions (elimination reactions).
	3	▪ Electrophilic substitution and mechanism. Reactions of electrophilic addition, orientation, and stereochemistry.
	4	▪ Pericyclic reactions: cycloadditions. Using organometallic reagents to make C–C bonds.
	5	▪ Formation of enols, enolates and ester enolates, reactions of enols (α-halogenation, reactions of silyl enol ethers).
	6	▪ Reactions of enolates with carbonyl compounds (the aldol and Claisen reactions, cross-condensations).
	7	▪ Alkylation of enolates, alkylation of nitriles, choice of electrophile for alkylation. Alkylation of β-dicarbonyl compounds, Michael reaction.
	8	▪ Aromatic heterocycles 1: reactions. Aromatic heterocycles 2: synthesis.
	9	▪
	10	▪
	11	▪
	12	▪
	13	▪
	14	▪
	15	▪

	Java/Week	Tema/Topics – PRAKTIKA/PRACTICE
	1	▪ Introduction to Advanced Synthetic Organic Chemistry Worksheet.
	2	▪ The influence of parameters on elimination reaction.

3	▪	Dimerization – Synthesis of Benzhydryl ether.
4	▪	C-C bond formation from 1- acetylindole.
5	▪	Synthesis of n-butyl acetate.
6	▪	Reactions of ketones (halogenation).
7	▪	C-N bond formation from acetonitrile.
8	▪	Synthesis of 2-(Bromoacetamido)-5-nitrobenzophenone.
9	▪	Synthesis of 2-Azidoacetamido-5-nitrobenzophenone.
10	▪	Synthesis of 7-Nitro-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (Nitrazepam).
11	▪	C-C bond formation from β-dicarbonyl compounds under solvent-free reaction conditions.
12	▪	C-C bond formation from 2,3-Benzofuran under green reaction conditions.
13	▪	C-O bond formation from alcohols.
14	▪	The effect of the structure on the reactivity of alcohols.
15	▪	Halogenation methods of organic molecules under green reaction conditions.

Java/Week	Tema/Topics – SEMINARE/SEMINARS	
1	▪	
2	▪	
3	▪	
4	▪	
5	▪	
6	▪	
7	▪	
8	▪	Report writing on the selected organic compound.
9	▪	
10	▪	
11	▪	
12	▪	

13	▪
14	▪
15	▪

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

J. Clayden, N. Greeves, S. Warren, Organic Chemistry, Oxford University Press, Inc., New York 2001.
K. Peter, C. Vollhardt, Neil E. Schore, Organic Chemistry: Structure and Function, 8th edition, W.H. Freeman, New York, 2018.
Review articles including selected topics on synthetic chemistry (recent papers published in the last decade).

Materiali i nevojshëm për kurs/Librat tjera për lexim
Recommended Course Material(s)/Reading(s)/Other

S. Ege, Organic Chemistry: Structure and Reactivity, 5th edition, Houghton Mifflin, Boston, 2003.

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	**NUMRI/ NUMBER**	**Përqindja në gradim/ Percentage of Grade**
Pjesëmarrja/Attendance	1x	**5**
Perform/Performanca/ance	0	0
Laboratori/Laboratory	1x	**15**
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	1x	**5**
Detyrat e Shtëpisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop/Shkruarja e raportit/Report writng	1x	**5**
Vlerësim në mes-term/Midterm(s)	2x10	**20**
Vlerësimi final/Final	1x	**50**
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	**NUMRI NUMBER**	**Kohëzgjatja (orë) Duration (Hours)**	**Ngarkesa Totale Total WorkLoad**
Orë mësimi/	8x	3	24

Course Hours			
Laborator/ Laboratory	10x	2	20
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/ Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	131
Prezentim, seminar, workshop/ Shkruarja e raportit Presentations, Seminar, Workshop/Report writng	0	0	30
Projekt/ Project	15	3	45
Detyra të shtëpisë/ Homework Assignments	0	0	0
Kuize/ Quizzes	0	0	0
Vlerësim në Mesterm/ Midterm(s)	2	0.5	1
Vlerësim Final/ Final EXAM	1	1	1
Ngarkesa Totale/ Total WorkLoad			**252**
Ngarkesa Totale/30 Total Workload/ 30			**10.08**
ECTS			**10.0**

Lecturer

Name and surname: Dr. Njomza Ajvazi – Ass. Profesor.

Name of the course	Pharmaceutics and Drug Development	**3**
Year of study	I	
Semester	1.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	20
	Practical work:	20
	Project work:	0
	Report writing	0
Total contact hours:	40	
Independent study:	35	
Total hours:	75	
ECTS:	3.0	

Course Objectives

The objective of this course is to get acquainted with the legal and pharmacopoeia requirements regarding the production and quality control of pharmaceutical products, formulations and composition of pharmaceutical products, sterile product manufacturing technology, application routes, qualitative and quantitative analytical techniques, studies of sustainability etc.

Course Content

The course contains topics from the field of law and standard production and quality control literature, production technology, pharmaceutical product specifications, drug sustainability stents, and the definition of sustainability, quality and design in the development of new drugs.

Learning Outcomes of the Course

Knowledge and Understanding:

Intellectual skills

1 Self-directed learning

2 Application of the thesis in practice

3 Use of scientific literature, libraries, presentations and scientific abilities

Professional practical skills

1 Ability to explain phenomena

2 Acquiring knowledge passed

3 Use the Internet and submit it to an audience.

4 To use the scientific method

Transferable skills

1 Communication skills, including listening skills

2 Reflective practices

3 Teaching, presentation skills

	Attitudes and behaviour	
	1	confidentiality
	2	sensitivity
	3	Access to the patient's center
	4	Self Assessment
	5	Reflective practice
		COURSE OUTLINE/SCHEDULE (Weekly)
	1	Requirements for drug substances including solubility, impurities and stability .
	2	Quality requirements for drug products.
	3	Quality assessment of drug substances, excipients and drug products.
	4	Formulation and composition of drug products with regulation to technical production requirements as well as bioavailability.
	5	Selecting excipients.
	6	Production techniques including the special regulations for sterile drug products.
	7	Mid-Term Exam 1
	8	Alternative administration routes.
	9	Drug product specifications and Pharmacopoeia requirements.
	10	Quantitative and analytical techniques for drug substances and characterization techniques for physical characteristics of intermediate drug product and final drug products
	11	Process control and finished-goods control.
	12	Durability and stability studies.
	13	Quality by Design (QbD) in Drug Development.
	14	Mid-Term Exam 2
	15	Pharmaceutical manufacturing site visit
		PRACTICE
	1	• Solubility and impurity determination .
	2	• ICH explanation and guidelines interpretions.
	3	• Ibuprofen nanoparticles synthesis with co-solvent method.
	4	• Wet granulation of both nano and mili metric Ibuprofen.
	5	• Tableting of Ibuprofen granules.
	6	• Dissolution of Iburofen tablets and profilisation of tablets with different particle size.
	7	• Microcapsules making with gelatine and polymeric additives.
	8	• Study and evaluation of different world pharmacopoeia-s.
	9	• Analytic methods for particle size determination.Particle sixe distribution and EXCEL in results calculations.
	10	• NIR spectroscopy.Laser diffraction,BET,HPLC as methods and their application in manufacturing process.
	11	• Temperature effect on salicylic acid tablets stability.

12	•	QbD based design of given dosage forms. Students works in groups.
13	•	Microcapsules making with gelatine and polymeric additives.
14	•	Mid-Term Exam 2
15	•	Pharmaceutical manufacturing site visit

Resources

Materialiinevojshëmpërkurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

Materialiinevojshëmpërkurs/Librattjerapërlexim
Recommended Course Material(s)/Reading(s)/Other

Internet

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesagjatësemestrit / Semester Requirements	NUMRI/NUMBER	Përqindjanëgradim/ Percentage of Grade
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Laborato/Laboratori/ry	1	10
Provimipraktik/Practical exam	1	20
Punanëterren/Field Work	0	0
Internshipi special ikursit/Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëspisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësimnëmes-term/Midterm(s)	2*5	10
Vlerësimi final/Final	1	50
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	NUMRI NUMBER	Kohëzgjatja (orë) Duration (Hours)	NgarkesaTotale Total WorkLoad
Orëmësimi/ Course Hours	15	1.6	24
Laborator/ Laboratory	15	1.3	20
Provimpraktik/ Practical Exam	1	1	1

Internshipi special ikursit/Special Course Internship (Work Placement)	0	0	0
PunanëTerren/ Field Work	0	0	0
Orëtëmësimittëvetëdrejtuar/ Study Hours Out of Class	0	0	131
Prezentim, seminar, workshop/ Presentations,Seminar, Workshop	15	2	30
Projekt/ Project	15	3	45
Detyratështëpisë/ Homework Assignments	0	0	0
Kuize/ Quizzes	0	0	0
VlerësimnëMesterm/ Midterm(s)	2	0.5	1
Vlerësim Final/ Final EXAM	1	1	1
NgarkesaTotale/ Total WorkLoad			**253**
NgarkesaTotale/30 Total Workload/ 30			**10.1**
ECTS			**10.0**

Mësimdhënësi

Mësimdhësi: Prof. Asoc. ZehadinGashiD.Ph

Name of the course	Principles of Pharmacology	**5**
Year of study	I	
Semester	2.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	40
	Practical work:	6
	Project work:	20
	Report writing	20
Total contact hours:	86	
Independent study:	164	
Total hours:	250	
ECTS:	10.0	

Objektivat e kursit/Course Objectives

The course intends to offer the students a deep understanding of the pharmacology, by bringing together in a joint version the concepts from Anatomy, Pathology and Pharmacology.

Përmbajtja e kursit/Course Content

The course reviews the main pharmacokinetic concepts and focuses in deeper understanding of the pharmacodynamics

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

1	Review of basic anatomy, histology and citology
2	Concepts in physiology
3	Review the main concepts in pharmacokinetic and discuss the main pharmacokinetic parameteres
4	Understand the mechanism of action of some drug groups, as well as the molecular mechanisms of side effects
5	Calculate, estimate and discuss physiological and pharmacological parameters obtained from simulated experimental pharmacodynamic data
6	Discuss and explain pharmacology-related procedures and methods used in preclinical and clinical drug development

Shkathtësitë intelektuale/ Intellectual skills

1	Theoretical and practical engagement
2	Using different available library and online resources for independent learning

Shkathtësitë praktike profesionale/ Professional practical skills

1	Simulation of experimental procedures on the mouse heart, aorta, and intestine
4	Complex pharmacological calculations, understanding EC50, Emax and Therapeutic index
5	Data analysis, creating tables and graphs, and visual and oral data presentation

Shkathtësitë për transferimin e njohurive/ Transferable skills

1	Communication skills
2	Critical thinking, preparing small scientific projects, and presentation skills

Qëndrimet dhe sjelljet/ Attitudes and behaviour	
1	Assuring confidentiality
2	Building empathic views
3	Safety principles in the laboratory
4	Understanding, accepting and working through individual differences
5	Motivation towards self engagement, life-long learning and carrier considerations

PËRMBLEDHJA E KURSIT/ORARI (javor)

COURSE OUTLINE/SCHEDULE (Weekly)

Java/Week	Tema/Topics – LEKSIONE/LECTURES
1	▪ Introduction to pharmacology ▪ Basic concepts in pharmacodynamics and pharmacokinetics ▪ Cell-cell communication (autocrine, paracrine, endocrine, synaptic and direct cell-cell communication)
2	▪ Basic concepts how drugs act ▪ The concept of drug dose and dose-response curves
3	▪ Agonists ▪ Drug efficacy, maximal response and receptor saturation ▪ Drug potency, drug-receptor affinity and EC50
4	▪ Full and partial agonists ▪ Reversible neutral competitive antagonists (Emax and EC50) ▪ Irreversible antagonists (Emax and EC50) ▪ Reverse agonists (Emax and EC50) ▪ Ortosterik and alosterik drug binding to the receptor (Emax and EC50)
5	▪ Quantal dose-response curve ▪ Therapeutic index, therapeutic window and calculations ▪ Side effects, adverse drug reactions, and drug toxicity ▪ Drug safety
6	▪ Mid-term exam 1
7	▪ The pharmacodynamics of drug interactions ▪ Antagonism (pharmacodynamic, physiologic, and pharmacokinetic interactions) ▪ Potentiation (additive effect, synergism, and pharmacokinetic interactions)
8	▪ Basic concepts on drug targets ▪ Basic concepts on drug actions (molecular, biochemical, cellular, physiological and structural drug effects) ▪ Drug targets (receptors, ion transporters, ion channels, enzymes, cytockeleton, antibodies) ▪ Drug receptors
9	▪ GPCR (structure, G-proteins, cell signaling, GPCR desensitization)
10	▪ Desensitisation concepts (tachyphylaxis, downregulation, tolerance and adaptation) ▪ Receptor upregulation
11	▪ Nuclear receptors and gene expression ▪ Ion channels as drug targets ▪ Receptor tyrosine kinases
12	▪ Basic concepts of *in vitro* and *in vivo* pharmacological models
13	▪ Basic pharmacokinetic concepts ▪ Drug administration routes (advantages and disadvantages) ▪ Drug metabolism and elimination (liver and kidney as the main elimination organs, effect of pH and durg's physico-chemical characteristics on absorption and elimination)
14	▪ Basic pharmacokinetic parameters (Cmax, Tmax, AUC) ▪ Zero- and first-order drug elimination ▪ Bioavalability and bioequivalence

15	▪ Mid-term exam 2

Java/Week	Tema/Topics – PROJECT/PROJEKTI
1	▪ How to use online search machines
2	▪ Primary, secondary, and tertiary literature in research
3	▪ Introduction to organ bath studies and tissue preparation (mouse heart, aortic rings, intestines) - video assisted learning.
4	▪ Optimizing *in vitro* experimental conditions (pH and buffers, temperature, composition of solutions) ▪ Calculations and preparing the right concentration of solutions of adrenaline, acetylcholine, phentolamine, propranolol, atropine and verapamil
5	▪ Stimulation of the **aorta** by increasing concentrations of **adrenaline** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve
6	▪ Stimulation of the aorta by increasing concentrations of adrenaline in the presence of **propranolol** or **phentolamine** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve ▪ Analyzing the effect of selective α-receptor antagonist and β-receptor antagonist
7	▪ Stimulation of the aorta by increasing concentrations of acetylcholine alone or in the presence of different concentrations of **atropine** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve ▪ Analyzing the effect of acetylcholine on the aorta as well as the muscarinic receptor antagonist (atropine)
8	▪ Stimulation of the **heart** by increasing concentrations of adrenaline and acetylcholine (software simulation) ▪ Analyzing changes in the heart rate and ventricular pressure ▪ Creating tables and building semilogarithmic dose-response curve
9	▪ Stimulation of the heart by increasing concentrations of adrenaline and acetylcholine in the presence of antagonists such as propranolol, phentolamine and atropine (software simulation) ▪ Analyzing changes in the heart rate and ventricular pressure ▪ Creating tables and building semilogarithmic dose-response curve
10	▪ Stimulation of the **intestines** by increasing concentrations of adrenaline and **acetylcholine** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve
11	▪ The effect of **verapamil** on the intestines, and the **drug interaction** with adrenaline and acetylcholine (software simulation)
12	▪ Presentation skills, PPT organization and slide preparation ▪ Soft skills, dealing with presentation stress, attitude to the critics and answering questions
13	▪ Presentation and interpretation of the previously collected organ bath data 1
14	▪ Presentation and interpretation of the previously collected organ bath data 2
15	▪ Presentation and interpretation of the previously collected organ bath data 3

Java/Week	Tema/Topics – SEMINARE/SEMINARS
1	▪ Citology, cell membrane, ion potential, ion transporters (primary, secondary, active, passive transport), and ion channels
2	▪ Calcium as a second messenger

3	▪	The mechanism of cell contraction (cell signaling differences in skeletal muscle, cardiomyocites, and smooth muscle cells)
4	▪ ▪	The physiology of blood vessels (nitric oxide and the communication between endothelial cells and the smooth muscle layer of blood vessels) Atheriosclerosis
5	▪	Aspirin (molecular mechanisms for its antithrombotic effect)
6	▪	The cardiovascular system, hypertension, rennin-angiotensin-aldosterone system as a drug target
7	▪	Diabetes and drug therapy (drug mechanism of action)
8	▪	Molecular mechanisms of the immune response and possibilities of interfering with drug therapy
9	▪	Angiogenesis as a pharmacology target (tumor *vs.* tissue regeneration)
10	▪ ▪	*In vivo* animol models of disease Transgenic animal models
11	▪	Clinical trials (phases of clinical trials, study designs, placebo and nocebo effects, meta analysis)
12	▪ ▪	Chronic myeloid leukemia (CML) The whole story of Imatinib, from drug discovery to clinical approval (the mechanism of action)
13	▪	*In vivo* and *in vitro* pharmacokinetic models
14	▪	The pharmacokinetics of paracetamol, the effect of fast and fed state
15	▪	The pharmacokinetics of different aspirin formulations, the effect of dosage form

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

- Rang & Dale's Pharmacology – 9th Edition – Elsevier
(English and Albanian translation both available)
-Virtual PC program for Experimental Pharmacology
-PC
-LCD projector

Materiali i nevojshëm për kurs/Librat tjera për lexim
Recommended Course Material(s)/Reading(s)/Other

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	**NUMRI/ NUMBER**	**Përqindja në gradim/ Percentage of Grade**
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Raportet Laboratorike/Laboratory Reports	1	20
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëpisë/Homework Assignments	0	0

Prezentimi/Presentation	1	10
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	2	0
Vlerësimi final/Final	1	40
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	**NUMRI NUMBER**	**Kohëzgjatja (orë) Duration (Hours)**	**Ngarkesa Totale Total WorkLoad**
Orë mësimi/ Course Hours	0	0	40
Laborator/ Laboratory	0	0	6
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/ Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	164
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop, Report writing	0	0	20
Projekt/ Project	0	0	20
Detyra të shtëpisë/ Homework Assignments	0	0	0
Kuize/ Quizzes	0	0	0
Vlerësim në Mesterm/ Midterm(s)	0	0	1
Vlerësim Final/ Final EXAM	0	0	1
Ngarkesa Totale/ Total WorkLoad			**252**
Ngarkesa Totale/30 Total Workload/ 30			**10.08**
ECTS			**10.0**

Course professor: Nderim Kryeziu

Name, Surname

Remark: This Syllabus is provided in English and Albanian languages, as separate documents.

Name of the course	Principles and Practice of Bioanalysis	6
Year of study	I	
Semester	2.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	30
	Practical work:	55
	Project work:	0
	Report writing	0
Total contact hours:	85	
Independent study:	165	
Total hours:	250	
ECTS:	10.0	

Objektivat e kursit/Course Objectives

Creating theoretical and practical knowledge on the analytical control of pharmaceutical products.

Përmbajtja e kursit/Course Content

To enable students to understand and perform bioanalytical chemical work. Students should be able to understand the principles behind and use the analytical chemical instrumentation needed for high sensitivity analysis of samples of biological origin. Furthermore, students should know the capability and limitations of the individual analytical techniques with respect to selectivity and sensitivity.

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

1	Know and use a broad number of separation and detection principles as well as sample preparation techniques used for bioanalysis.
2	Judge and use the relevant original analytical chemical literature, handbooks and databases.
3	Develop new analytical chemical methods for analysing of samples of biological origin (e.g. urine, plasma, serum, faeces, saliva, synovial liquid, plant materials etc.)
4	Design sampling and storage protocols for in vivo studies of drug substances
5	Discuss and present the results of a chemical experiment.
6	

Shkathtësitë intelektuale/ Intellectual skills

1	Theoretical and practical engagement
2	Using different available library and online resources for independent learning

Shkathtësitë praktike profesionale/ Professional practical skills

1	separation and detection principles as well as sample preparation techniques used for bioanalysis
4	Develop new analytical chemical methods for analysing of samples of biological origin
5	Data analysis, creating tables and graphs, and visual and oral data presentation

Shkathtësitë për transferimin e njohurive/ Transferable skills

1	Communication skills
2	Critical thinking, preparing small scientific projects, and presentation skills

Qëndrimet dhe sjelljet/ Attitudes and behaviour

1	Building empathic views
2	Safety principles in the laboratory
3	Understanding, accepting and working through individual differences
4	Motivation towards self engagement, life-long learning and carrier considerations
5	

PËRMBLEDHJA E KURSIT/ORARI (javor)

COURSE OUTLINE/SCHEDULE (Weekly)

Java/Week	Tema/Topics – LEKSIONE/LECTURES
1	Physicochemical Properties of Drugs and Metabolites and Their Impact on Bioanalysis
2	Sample Preparation
3	Basic HPLC Theory and Practice
4	HPLC Optimisation
5	HPLC Detectors
6	Gas Chromatography: What It Is and How We Use It
7	Thin-Layer Chromatography
8	Immunoassay Techniques
9	Automation of Sample Preparation
10	Fundamental Aspects of Mass Spectrometry
11	Quantitative LC –MS
12	Mass Spectrometric Identification of Metabolites
13	Nuclear Magnetic Resonance In Drug Metabolism
14	Metabolite Isolation
15	Strategy for the Development of Quantitative Bioanalytical Procedures

Java/Week	Tema/Topics – PRAKTIKA/ PRACTICE
1	Physicochemical Properties of Drugs and Metabolites and Their Impact on Bioanalysis
2	Sample Preparation
3	Basic HPLC Theory and Practice
4	HPLC Optimisation

5	HPLC Detectors
6	Gas Chromatography: What It Is and How We Use It
7	Thin-Layer Chromatography
8	Immunoassay Techniques
9	Automation of Sample Preparation
10	Fundamental Aspects of Mass Spectrometry
11	Quantitative LC –MS
12	Mass Spectrometric Identification of Metabolites
13	Nuclear Magnetic Resonance In Drug Metabolism
14	Metabolite Isolation
15	Strategy for the Development of Quantitative Bioanalytical Procedures

Java/Week	Tema/Topics – SEMINARE/SEMINARS
1	▪
2	▪
3	▪
4	▪
5	▪
6	▪
7	▪
8	▪
9	▪
10	▪
11	▪
12	▪
13	▪
14	▪
15	▪

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

- Richard F. Venn (Ed.) Principles and Practice of Bioanalysis. 2nd Ed. 2008, CRC Press.
- Harris, D.C. Quantitative Chemical Analysis (2007). Publisher: W H Freeman ISBN: 0716770415. 7th ed.
- FDA guideline: Validation of Bioanalytical methods.

- The European Pharmacopoeia: Chromatography
- Additional course materials such as manuals and scientific papers are availabe from the course homepage

Materiali i nevojshëm për kurs/Librat tjera për lexim **Recommended Course Material(s)/Reading(s)/Other**

SISTEMI VLERËSIMIT/EVALUATION SYSTEM		
Kërkesa gjatë semestrit / **Semester Requirements**	**NUMRI/** **NUMBER**	**Përqindja në gradim/** **Percentage of Grade**
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Raportet Laboratorike/Laboratory Reports	1	20
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëpisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	2*10	20
Vlerësimi final/Final	1	50
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT **ECTS/STUDENT WORKLOAD**			
AKTIVITETET/ACTIVITIES	**NUMRI** **NUMBER**	**Kohëzgjatja (orë)** **Duration (Hours)**	**Ngarkesa Totale** **Total WorkLoad**
Orë mësimi/ Course Hours	15	2	30
Laborator/ Laboratory	15	3.7	55
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/ Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	165
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop, Report writing	0	0	0
Projekt/ Project	0	0	0
Detyra të shtëpisë/	0	0	0

Homework Assignments				
Kuize/ Quizzes	0	0	0	
Vlerësim në Mesterm/ Midterm(s)	2	0.5	1	
Vlerësim Final/ Final EXAM	1	1	1	
Ngarkesa Totale/ Total WorkLoad				**252**
Ngarkesa Totale/30 Total Workload/ 30				**10.08**
ECTS				**10.0**

Course professor: Adnan Bozalia

Name, Surname

Name of the course	In-vitro Techniques in Biochemistry and Pharmacology	**7**
Year of study	I	
Semester	2.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	15
	Practical work:	45
	Project work:	0
	Report writing	27
Total contact hours:	87	
Independent study:	88	
Total hours:	175	
ECTS:	7.0	

Objektivat e kursit/Course Objectives

The course intends to introduce the students to basic principles of *in vitro* studies, experimental designs and laboratory approaches to answer clinical and research based scientific questions.

Përmbajtja e kursit/Course Content

The course reviews the main experimental conditions for *in vitro* experiments, and introduces common laboratory techniques in biochemistry and pharmacology.

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

1. Basic laboratory skills and safety principles
2. Calculations and preparation of necessary solutions
3. Organ bath technique
4. Enzyme kinetics
5. Common biochemical techniques
6. Calculate, estimate and discuss physiological, pharmacological and biochemical parameters obtained from simulated experimental data

Shkathtësitë intelektuale/ Intellectual skills

1. Theoretical and practical engagement
2. Using different available library and online resources for independent learning

Shkathtësitë praktike profesionale/ Professional practical skills

1. Simulation of experimental procedures on the mouse intestine, heart, and aort
2. Enzyme kinetics
3. Common laboratory techniques (antibiogram, ELISA, PCR, flow cytometry)
4. Introduction to cell culture
5. Complex pharmacological calculations, understanding EC50, Emax and Therapeutic index

Shkathtësitë për transferimin e njohurive/ Transferable skills

1. Communication skills

2	Critical thinking, preparing small scientific projects, and presentation skills
Qëndrimet dhe sjelljet/ Attitudes and behaviour	
1	Assuring confidentiality
2	Building empathic views
3	Safety principles in the laboratory
4	Understanding, accepting and working through individual differences
5	Motivation towards self engagement, life-long learning and carrier considerations

PËRMBLEDHJA E KURSIT/ORARI (javor)

COURSE OUTLINE/SCHEDULE (Weekly)

Java/Week	Tema/Topics – LEKSIONE/LECTURES
1	▪ Reviewing basic concepts in biochemistry and pharmacology ▪ Introduction to *in vitro* principles
2	▪ Materials collected from study subjects (patients or animals) use for *in vitro* studies
3	▪ Organ bath technique, experimental conditions *in vitro,* and harvesting animal organs
4	▪ Reviewing heart, aorta, and intestine histology and physiology ▪ Reviewing sympathetic and parasympathetic nervous system mediators, their agonists and antagonists
5	▪ Cell culture technique (video assisted) ▪ Common instruments used in a cell culture laboratory (centrifuges, laminary flow box, incubators, pipettes, water baths) ▪ Preparation of endothelial cells from umbilical veins and mouse lungs
6	▪ Mid-term exam 1
7	▪ Method validation and quality control (accuracy, precision, reliability, and robustness) ▪ Quantitative *vs.* qualitative analysis
8	▪ Antibiogram as a tool in pharmacology to study antibiotic efficacy
9	▪ Antibodies in the *in vitro* approaches and immunoassays
10	▪ Enzymes as tool in the *in vitro* studies ▪ Review of enzyme kinetics (the effect of pH, temperature, substrate and enzyme concentration)
11	▪ ELISA (direct, indirect, and sandwich ELISA principles)
12	▪ Flow cytometry
13	▪ Review of urine formation in the kidneys ▪ Proper urine sample collection ▪ Urine analysis (macroscopic examination, chemical analysis, mikroskopic examination, cytological analysis) ▪ Pregnancy hCG testing in urine
14	▪ Review of normal DNA replication ▪ Polimerase chain reaction (PCR) principles ▪ Gel electrophoresis
15	▪ Mid-term exam 2

Java/Week	Tema/Topics – PRAKTIKA/PRACTICE
1	▪ How to use online search machines ▪ Primary, secondary, and tertiary literature in research ▪ Common laboratory concepts and safety ▪ Sterilization and disinfection techniques
2	▪ Introduction to organ bath studies and tissue preparation (mouse heart, aortic rings, intestines) - video assisted learning
3	▪ Calculations and preparation of solutions of proper pH, osmolarity, and stimulant concentration ▪ Optimizing *in vitro* experimental conditions (pH and buffers, temperature, composition of solutions)
4	▪ Stimulation of the **aorta and intestine** by increasing concentrations of **adrenaline and acetylcholine** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve
5	▪ Stimulation of the aorta and intestine by increasing concentrations of adrenaline and acetylcholine in the presence of **propranolol**, **phentolamine, or atropine** (software simulation) ▪ Creating tables and building semilogarithmic dose-response curve ▪ Analyzing the effect of selective α-, β-, and M-receptor antagonist
6	▪ Stimulation of the **heart** by increasing concentrations of adrenaline and acetylcholine (software simulation) ▪ Analyzing changes in the heart rate and ventricular pressure ▪ Creating tables and building semilogarithmic dose-response curve
7	▪ Presentation and interpretation of the previously collected organ bath data 1
8	▪ Presentation and interpretation of the previously collected organ bath data 2
9	▪ Cell culture technique (software simulation)
10	▪ Enzyme kinetics software simulations ▪ Determining Vmax and Km through Lineweaver-Burk equation
11	▪ Enzymes as drug targets (software simulations) ▪ Drugs as competitive and non-competitive enzyme inhibitors
12	▪ Visit to the microbiology lab and antibiogram analysis
13	▪ Visit to the biochemistry lab and reviewing ELISA instruments and technique
14	▪ Microscopic urine analysis and urine test strip
15	▪ PCR technique (software simulation)

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

- Rang & Dale's Pharmacology – 9th Edition – Elsevier
(English and Albanian translation both available)
-Study material provided separately for each laboratory technique
-Virtual PC program for Experimental Pharmacology and Biochemistry
-PC
-LCD projector

Materiali i nevojshëm për kurs/Librat tjera për lexim
Recommended Course Material(s)/Reading(s)/Other

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	NUMRI/ NUMBER	Përqindja në gradim/ Percentage of Grade
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Raportet Laboratorike/Laboratory Reports	1	20
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëpisë/Homework Assignments	0	0
Prezentimi/Presentation	1	10
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	2	0
Vlerësimi final/Final	1	40
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	NUMRI NUMBER	Kohëzgjatja (orë) Duration (Hours)	Ngarkesa Totale Total WorkLoad
Orë mësimi/Course Hours	15	1	15
Laborator/Laboratory	15	3	45
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	88
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop, Report writing	0	0	27
Projekt/Project	0	0	0
Detyra të shtëpisë/Homework Assignments	0	0	0
Kuize/Quizzes	0	0	0
Vlerësim në Mesterm/Midterm(s)	2	0.5	1
Vlerësim Final/Final EXAM	1	1	1
Ngarkesa Totale/Total WorkLoad			**177**
Ngarkesa Totale/Total Workload/ 30			**7.08**
ECTS			**7.0**

Course professor: Nderim Kryeziu

Name, Surname

Name of the course	Pharmacology: From Physiology to Therapy	9
Year of study	II	
Semester	3.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	60
	Practical work:	5
	Project work:	35
	Report writing	0
Total contact hours:	100	
Independent study:	100	
Total hours:	200	
ECTS:	8.0	

Objektivat e kursit/Course Objectives

This course has two overall goals and two different methods of assessment of success of these goals (see later assessment section):

- **To ensure students gain fundamental knowledge relevant to pharmaceutical science:**
  Students must attain a basic familiarity with human physiology and understanding of the mechanisms of action of pharmacological management of disorders. Accordingly, this course is designed to instil in students an anatomical and physiological knowledge about the structure and function of organs, including the effects of commonly-appearing diseases upon organ systems. On the basis of this knowledge, students should understand not only the effects of pharmacotherapies, but also the mode of action and the principles behind safe and rational use of drugs. This goal will be assessed with a written exam.

- **To ensure students gain skills to perform a task within pharmaceutical sciences:**
  Students must learn how to apply knowledge they have acquired in pensum material to real world problems. This goal will be assessed by active participation in tutorials and projects necessitating completion of a specific product based task. Tutorials and projects are designed to draw from pensum material so that students gain experience putting learned material into practical use. Attendance at, and participation in, tutorials and projects is expected to solidify and assist in retention of pensum material. Within six main themes, students will be expected to create a product (oral presentation or written report). Within two of these six themes, students will be expected in a project to read a basic research paper directly relevant to pensum material. They will present this paper exhibiting the ability to extract relevant information. By conducting tutorial and project tasks, students will be encouraged to exhibit intellectual independence and choice.

Përmbajtja e kursit/Course Content

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

	1	Explain in depth the basic function of major organs. The latter includes the modulation and feedback systems involved in maintaining homeostasis
	2	Explain the consequences of pathophysiological disturbances in single organs and organ systems, including drugs to treat these disturbances.
	3	Reflect on the target for the action, the indication and contraindication for treatment with commonly used drugs
	4	Be able to perform basic calculations based on kidney and respiratory lectures and tutorials.
	5	Explain virus biology and potential strategies for development of anti-viral pharmacological agents
	6	Be able to communicate the properties of classes of commonly used drugs used for treatment of major diseases
	7	Propose a relevant pharmacological intervention for a patient with a known disease on the basis of a relevant patient description
	8	Read a primary research report related to the lecture material with the ability to extract relevant information and biomedical significance
	Shkathtësitë intelektuale**/** Intellectual skills	
	1	Theoretical and practical engagement
	2	Using different available library and online resources for independent learning
	Shkathtësitë praktike profesionale/ Professional practical skills	
	1	Be able to perform basic calculations based on kidney and respiratory lectures and tutorials
	2	Be able to communicate the properties of classes of commonly used drugs used for treatment of major diseases
	3	Propose a relevant pharmacological intervention for a patient with a known disease on the basis of a relevant patient description
	4	Read a primary research report related to the lecture material with the ability to extract relevant information and biomedical significance
	5	
	Shkathtësitë për transferimin e njohurive/ Transferable skills	
	1	Communication skills
	2	Critical thinking, preparing small scientific projects, and presentation skills
	Qëndrimet dhe sjelljet/ Attitudes and behaviour	
	1	Assuring confidentiality
	2	Building empathic views
	3	Safety principles in the laboratory
	4	Understanding, accepting and working through individual differences
	5	Motivation towards self engagement, life-long learning and carrier considerations
	PËRMBLEDHJA E KURSIT/ORARI (javor) COURSE OUTLINE/SCHEDULE (Weekly)	
	Java/Week	Tema/Topics – LEKSIONE/LECTURES
	1	▪
	2	▪
	3	▪

4	▪
5	▪
6	▪
7	▪
8	▪
9	▪
10	▪
11	▪
12	▪
13	▪
14	▪
15	▪

Java/Week	Tema/Topics – PRAKTIKA/PRACTICE
1	▪
2	▪
3	▪
4	▪
5	▪
6	▪
7	▪
8	▪
9	▪
10	▪
11	▪
12	▪
13	▪
14	▪
15	▪

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

- Rang & Dale's Pharmacology – 9th Edition – Elsevier
  (English and Albanian translation both available)
-Study material provided separately for each laboratory technique
-Virtual PC program for Experimental Pharmacology and Biochemistry
-PC
-LCD projector

Materiali i nevojshëm për kurs/Librat tjera për lexim
Recommended Course Material(s)/Reading(s)/Other

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	NUMRI/ NUMBER	Përqindja në gradim/ Percentage of Grade
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Raportet Laboratorike/Laboratory Reports	1	20
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëpisë/Homework Assignments	0	0
Prezentimi/Presentation	1	10
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	2*5	10
Vlerësimi final/Final	1	50
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	NUMRI NUMBER	Kohëzgjatja (orë) Duration (Hours)	Ngarkesa Totale Total WorkLoad
Orë mësimi/Course Hours	15	4	60
Laborator/Laboratory	5	1	5
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	100
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop, Report writing	0	0	0
Projekt/Project	0	0	35

Detyra të shtëpisë/Homework Assignments	0	0	0
Kuize/Quizzes	0	0	0
Vlerësim në Mesterm/Midterm(s)	2	0.5	1
Vlerësim Final/Final EXAM	1	1	1
Ngarkesa Totale/Total WorkLoad			**202**
Ngarkesa Totale/Total Workload/ 30			**8.08**
ECTS			**8.0**

Course professor: Nderim Kryeziu

Name, Surname

Name of the course	Pharmacokinetics and Pharmacodynamics	**10**
Year of study	II	
Semester	3.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	50
	Practical work:	0
	Project work:	0
	Report writing	30
Total contact hours:	80	
Independent study:	70	
Total hours:	150	
ECTS:	6.0	

Objektivat e kursit/Course Objectives

The objective of the course is to provide insight and hands-on experience with pharmacokinetic and –dynamic data analysis, based on different examples of plasma concentration-time course of drug and link to therapeutic response. The modelling software Phoenix WinNonlin and Microsoft Excel will be used for data analysis. The students will be introduced to variability in patient populations and how PKPD analysis can be used to describe variability in response in different patient segments and in drug research and development within the pharmaceutical industry. Furthermore they will obtain knowledge about dosing strategies in different clinical situations.

Përmbajtja e kursit/Course Content

Pharmacokinetics (PK) and pharmacodynamics (PD) is a quantitative description of the interaction between a drug and the body over time and forms the basis for choice of drug and decisions on dose magnitude and dosing interval.

Rezultatet mësimore të kursit/Learning Outcomes of the Course

Njohuritë dhe çështjet që duhet të kuptohen/ Knowledge and Understanding:

1	Identify and characterize the basic pharmacokinetic and pharmacodynamic properties of a given drug from data on two or more of the following variables dose, time, plasma concentration and response data
2	Analyse PKPD data that can be translated into the drug treatment of individual patients and groups of patients
3	
4	
5	
6	
7	
8	

Shkathtësitë intelektuale/ Intellectual skills

1	Theoretical and practical engagement
2	Using different available library and online resources for independent learning

	Shkathtësitë praktike profesionale/ Professional practical skills	
1	Be able to perform basic calculations of PK parameters	
2	Analyse PK data	
3	Analyse PD data	
4		
5		
	Shkathtësitë për transferimin e njohurive/ Transferable skills	
1	Communication skills	
2	Critical thinking, preparing small scientific projects, and presentation skills	
	Qëndrimet dhe sjelljet/ Attitudes and behaviour	
1	Building empathic views	
2	Safety principles in the laboratory	
3	Understanding, accepting and working through individual differences	
4	Motivation towards self engagement, life-long learning and carrier considerations	
5		

PËRMBLEDHJA E KURSIT/ORARI (javor)

COURSE OUTLINE/SCHEDULE (Weekly)

Java/Week	Tema/Topics – LEKSIONE/LECTURES
1	▪ Therapeutic relevance. Fundamental concepts and terminology
2	▪ Kinetics Following an Intravenous Bolus Dose
3	▪ Elimination
4	▪ Kinetics Following an Extravascular Dose.
5	▪ Absorption. Response Following a Single Dose
6	▪ Therapeutic regimens. Therapeutic Window. Constant-Rate Input
7	▪ Multiple-Dose Regimens
8	▪ MidTerm Exam-1
9	▪ Individualization of therapy
10	▪ Initiating and Managing Therapy
11	▪ Distribution Kinetics
12	▪ Metabolites and Drug Response
13	▪ Protein Drugs
14	▪ Prediction and Refinement of Human Kinetics from In Vitro, Preclinical, and Early Clinical Data
15	▪ MidTerm Exam-2

Java/Week	Tema/Topics – Shkruarja e raportit/REPORT WRITING
1	▪ Ionization and the pH Partition Hypothesis
2	▪ Kinetics Following an Intravenous Bolus Dose
3	▪ Plasma-to-Blood Concentration Ratio
4	▪ Elimination
5	▪ Well-stirred Model of Hepatic Clearance
6	▪ Assessment of AUC
7	▪ Absorption Kinetics
8	▪ Wagner-Nelson Method
9	▪ Multiple-Dose Regimens
10	▪ Multiple-Dose Regimens
11	▪ Amount of Drug in Body on Accumulation to Plateau
12	▪ Distribution of Drugs Extensively Bound to Plasma Proteins
13	▪ Study Problems
14	▪ Study Problems
15	▪ Study Problems

Resurset/Resources

Materiali i nevojshëm për kurs/Librat
Required Course Material(s)/Reading(s)/Text Book(s)

- M. Rowland and T. Tozer, Clinical Pharmacokinetics and Pharmacodynamics, ed. 4, 2011
- Notes and lecture hand-outs available on the course homepage

-PC
-LCD projector

Materiali i nevojshëm për kurs/Librat tjera për lexim
Recommended Course Material(s)/Reading(s)/Other

SISTEMI VLERËSIMIT/EVALUATION SYSTEM

Kërkesa gjatë semestrit / Semester Requirements	NUMRI/ NUMBER	Përqindja në gradim/ Percentage of Grade
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Raportet Laboratorike/Laboratory Reports	1	20
Provimi praktik/Practical exam	0	0
Puna në terren/Field Work	0	0

Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëpisë/Homework Assignments	0	0
Prezentimi/Presentation	1	10
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	0	0
Vlerësim në mes-term/Midterm(s)	2*5	10
Vlerësimi final/Final	1	50
TOTAL		**100**

ECTS /NGARKESA E STUDENTIT
ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	NUMRI NUMBER	Kohëzgjatja (orë) Duration (Hours)	Ngarkesa Totale Total WorkLoad
Orë mësimi/Course Hours	15	3.3	50
Laborator/Laboratory	0	0	0
Provim praktik/ Practical Exam	0	0	0
Internshipi special i kursit/ Special Course Internship (Work Placement)	0	0	0
Puna në Terren/Field Work	0	0	0
Orë të mësimit të vetëdrejtuar/ Study Hours Out of Class	0	0	70
Prezentim, seminar, workshop/ Presentations, Seminar, Workshop, Report writing	15	2	30
Projekt/Project	0	0	0
Detyra të shtëpisë/Homework Assignments	0	0	0
Kuize/Quizzes	0	0	0
Vlerësim në Mesterm/Midterm(s)	2	0.5	1
Vlerësim Final/Final EXAM	1	1	1
Ngarkesa Totale/Total WorkLoad			**152**
Ngarkesa Totale/Total Workload/ 30			**6.08**
ECTS			**6.0**

Course professor: Blerim Krasniqi, Nderim Kryeziu

Name, Surname

Name of the course	Advanced Manufacturing of Pharmaceuticals	**11**
Year of study	II	
Semester	3.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	30
	Practical work:	14
	Project work:	36
	Report writing	0
Total contact hours:	80	
Independent study:	70	
Total hours:	150	
ECTS:	6.0	

Course Objectives

Objectives of this course are topics of pharmaceutical production operations, synthesis and crystallization of small molecules, macromolecular systems, granulation, tableting, drying and freezing technology, analytical technology of pharmaceuticals and finished products, chemometry etc.

Course Content

The course contains the theoretical part of technological production operations, quality control, synthesis of pharmaceutical design projects and visit pharmaceutical manufacturers.

Learning Outcomes of the Course

Knowledge and Understanding**:**

Intellectual skills

1	• Be able to analyse the critical unit operations used in manufacturing medicinal products
2	• Understand the importance of formulation design in relation to manufacturing according to Quality by Design (QbD) principles
3	• Have insight into pharmaceutical quality systems, risk management techniques and plant design of pharmaceutical manufacturing sites
4	• Have acquired skills in performing basic Design of Experiments (DoE) and multivariate data analysis
5	• Have acquired skills in applying the general principles of physical modelling related to manufacturing of pharmaceuticals.

Professional practical skills

1	Phenomena interpreting skills
2	Internet usage and mass presentations.

3	Using Scientific methodology
4	
Transferable skills	
1	Communication skills, including listening skills
2	Praktikat reflektive
3	Teaching, presentation skills
Attitudes and behaviour	
1	Confidentiality
2	Sensibility
3	Patient focused
4	Self estimation
5	Reflective
	COURSE OUTLINE/SCHEDULE (Weekly)
	LESSONS
1	• Unit operations used in manufacturing of pharmaceuticals
2	• Manufacturing of small molecules (synthesis and crystallization)
3	• Manufacturing of macromolecular system (fermentation and related separation technologies)
4	• introduction of secondary manufacturing steps
5	• Granulation, tableting and coating,
6	• Spray/freeze drying technologies for macromolecular systems
7	• Process analytical technologies (PAT)
8	• Mid-Term Exam 1
9	• Quality by Design tools - Design of Experiments (DoE) and chemometrics
10	• General structure of pharmaceutical quality systems and basic risk management approaches
11	• Plant design of pharmaceutical manufacturing sites
12	• Projects
13	• Projects
14	• Visit to the factory
15	• Mid-Term Exam 2
	PRACTICE
1	• Rheology of pharmaceutical ingredients
2	• Pharmaceutical water.ION exchange and reverse osmosis conductometry and TOC
3	• Chemical synthesis, CSTR and PFR.Calculations
4	• Biostats and fermentation tanks.Disagn and aeration methods.Up stram and Down stream insulin manufacturing
5	• PAT in granulation technology.Temperature,humidity and NIR sensors
6	• Freeze drying systems.Lyophilsation technique

7	•	Liposomes and manufacturing
8	•	Facility design clean rooms,classiffication and air exchange
9	•	Aseptic manufacturing vs final sterilisation
10	•	GMP GLP ISO Quality management systems
11	•	Projects
12	•	Projects
13	•	Projects
14	•	Visit to the factory
15	▪	Mid-Term Exam

Resources

Required Course Material(s)/Reading(s)/Text Book(s)

Recommended Course Material(s)/Reading(s)/Other

Internet

EVALUATION SYSTEM

Kërkesagjatësemestrit / Semester Requirements	**NUMRI/NUMBER**	**Përqindjanëgradim/ Percentage of Grade**
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Laborato/Laboratori/ry	0	0
Provimipraktik/Practical exam	1	20
Punanëterren/Field Work	0	0
Internshipi special ikursit/Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëspisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	0	0
Seminaret; Workshopet/Seminar;Workshop	2	5
Vlerësimnëmes-term/Midterm(s)	2	10
Vlerësimi final/Final	1	40
TOTAL		**100**

ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	**NUMRI NUMBER**	**Kohëzgjatja (orë) Duration (Hours)**	**NgarkesaTotale Total WorkLoad**
Orëmësimi/	15	2	30

Course Hours				
Laborator/ Laboratory		14	1	14
Provimpraktik/ Practical Exam		1	1	1
Internshipi special ikursit/Special Course Internship (Work Placement)		0	0	0
PunanëTerren/ Field Work		0	0	0
Orëtëmësimittëvetëdrejtuar/ Study Hours Out of Class		0	0	70
Prezentim, seminar, workshop/ Presentations,Seminar, Workshop		0	0	0
Projekt/ Project		1	1	1
Detyratështëpisë/ Homework Assignments		0	0	0
Kuize/ Quizzes		0	0	0
VlerësimnëMesterm/ Midterm(s)		2	0.5	1
Vlerësim Final/ Final EXAM		1	1	1
	NgarkesaTotale/ Total WorkLoad			**154**
	NgarkesaTotale/30 Total Workload/ 30			**6.1**
	ECTS			**6.0**

Mësimdhënësi

Mësimdhësi: Prof. Asoc. ZehadinGashiD.Ph

Name of the course	Research Methods in Pharmacy	**12**
Year of study	II	
Semester	3.	
Status of course (O/E):	Obligatory (O)	

No. of teaching hours	Lecture:	40
	Practical work:	30
	Project work:	35
	Report writing	20
Total contact hours:	125	
Independent study:	125	
Total hours:	250	
ECTS:	10.0	

Course Objectives

The objective of this course is to develop the participants' methodical and practical skills in phrasing research questions in social and clinical pharmacy and designing an evidence based study using quantitative and/or qualitative research methods.

Course Content

Learning Outcomes of the Course

Knowledge and Understanding:

Intellectual skills

1
- After completing the study unit the students are expected to have gained a thorough and practical knowledge of how to phrase research questions in social and clinical pharmacy and choose the appropriate research design. Furthermore the students will master the choice between and the use of both qualitative and quantitative research methods within clinical pharmacy and social pharmacy with relevance for Master's thesis and future paid employment within the field of medicine.

Professional practical skills

1 Phenomena interpreting skills

2 Using Scientific methodology

3

4

Transferable skills

1 Communication skills, including listening skills

2 Reflective practice

3 Teaching, presentation skills

Attitudes and behaviour

1 Confidentiality

2	Sensibility
3	Patient focused
4	Self estimation
5	Reflective
	COURSE OUTLINE/SCHEDULE (Weekly)
	LESSONS
1	Investigating health services and health: the scope of research. Evaluating health services: multidisciplinary collaboration
2	Social research on health: sociological and psychological concepts and approaches
3	Health needs and their assessment: demography and epidemiology
4	Costing health services: health economics
5	The philosophy, theory and practice of research. The philosophical framework of measurement
6	The philosophical framework of measurement
7	The principles of research
8	Quantitative research: sampling and research methods. Sample size and sampling for quantitative research
9	Quantitative research: surveys
10	Quantitative research: experiments and other analytical methods of investigation
11	Sample selection and group assignment methods in experiments and other analytic methods
12	The tools of quantitative research. Data collection methods in quantitative research: questionnaires, interviews and their response rates
13	Questionnaire design. Techniques of survey interviewing. Preparation of quantitative data for coding and analysis
14	Qualitative and combined research methods, and their analysis. Unstructured and structured observational studies
15	Unstructured interviewing and focus groups. Other methods using both qualitative and quantitative approaches: case studies, consensus methods, action research and document research
	PRACTICE
1	Investigating health services and health: the scope of research. Evaluating health services: multidisciplinary collaboration
2	Social research on health: sociological and psychological concepts and approaches
3	Health needs and their assessment: demography and epidemiology
4	Costing health services: health economics
5	The philosophy, theory and practice of research. The philosophical framework of measurement
6	The philosophical framework of measurement
7	The principles of research
8	Quantitative research: sampling and research methods. Sample size and sampling for quantitative research
9	Quantitative research: surveys
10	Quantitative research: experiments and other analytical methods of investigation
11	Sample selection and group assignment methods in experiments and other analytic methods
12	The tools of quantitative research. Data collection methods in quantitative research: questionnaires, interviews and their response rates

13	Questionnaire design. Techniques of survey interviewing. Preparation of quantitative data for coding and analysis
14	Qualitative and combined research methods, and their analysis. Unstructured and structured observational studies
15	Unstructured interviewing and focus groups. Other methods using both qualitative and quantitative approaches: case studies, consensus methods, action research and document research

Resources

Required Course Material(s)/Reading(s)/Text Book(s)

PC
LCD
Table

- Ann Bowling. Research Methods in Health. Open University Press, 2009. ISBN 9780335233649

Recommended Course Material(s)/Reading(s)/Other

Internet

EVALUATION SYSTEM

Kërkesagjatësemestrit / Semester Requirements	NUMRI/NUMBER	Përqindjanëgradim/ Percentage of Grade
Pjesëmarrja/Attendance	1	5
Perform/Performanca/ance	1	5
Laborato/Laboratori/ry	1	10
Provimipraktik/Practical exam	0	0
Punanëterren/Field Work	0	0
Internshipi special ikursit/Special Course Internship (Work Placement)	0	0
Kuizet/Quizzes	0	0
Detyrat e Shtëspisë/Homework Assignments	0	0
Prezentimi/Presentation	0	0
Projekti/Project	1	10
Seminaret; Workshopet/Seminar;Workshop	1	10
Vlerësimnëmes-term/Midterm(s)	2*5	10
Vlerësimi final/Final	1	50
TOTAL		**100**

ECTS/STUDENT WORKLOAD

AKTIVITETET/ACTIVITIES	NUMRI NUMBER	Kohëzgjatja (orë) Duration (Hours)	NgarkesaTotale Total WorkLoad
Orëmësimi/ Course Hours	15	2.7	40
Laborator/ Laboratory	15	2	30

Provimpraktik/ Practical Exam	0	0	0
Internshipi special ikursit/Special Course Internship (Work Placement)	0	0	0
PunanëTerren/ Field Work	0	0	0
Orëtëmësimittëvetëdrejtuar/ Study Hours Out of Class	0	0	125
Prezentim, seminar, workshop/ Presentations,Seminar, Workshop	15	1.3	20
Projekt/ Project	15	2.3	35
Detyratështëpisë/ Homework Assignments	0	0	0
Kuize/ Quizzes	0	0	0
VlerësimnëMesterm/ Midterm(s)	2	0.5	1
Vlerësim Final/ Final EXAM	1	1	1
NgarkesaTotale/ Total WorkLoad			**252**
NgarkesaTotale/30 Total Workload/ 30			**10.08**
ECTS			**10.0**

Mësimdhënësi

Mësimdhësi: Prof. Ass. Mimoza Zhubi

Elective courses

Biopharmaceutics (E)

Short description:
The course covers theoretical biomolecular drug discovery as a central part of contemporary and future drug discovery efforts in academia and in the biotech and pharmaceutical industry. The identification, discovery, exploitation and development of biomolecules such as nucleic acids, proteins and larger peptides as (potential) medical drugs is taught and discussed through literature examples from the discovery, development and/or clinical phase, with special emphasis on the discovery phase, and the consequences of decisions made here.

Aims and Course outcomes

At the end of the course the student is expected to have gained an understanding of biomolecular drug discovery relating to the mechanism of action of selected peptide, protein and nucleic acid drugs, the principles and methods employed for *in vivo* delivery of such molecules as well as an understanding of their general properties in terms of pharmacokinetics and bioavailability.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Essay in the format of a scientific (review) paper based on literature studies on a subject agreed upon with the teacher and approved by the course director.(Size, no more than 50.000 characters including spaces).

Examiners:

Course Teacher(s) and external examiner

Teaching tools:
PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature
Pharmacokinetics and Pharmacodynamics of Biotech Drugs. B. Meibohm, Ed. Wiley-VCH, 2006. Scientific articles and notes distributed during the course.

Structural and Computational Medicinal Chemistry (E)

Short description:
The course is relevant for research within the drug discovery area and other areas where it is important to:

- have knowledge about experimental and theoretical methods that can be used to analyze molecular characteristics of biologically important molecules
- understand the interactions between ligands and biomacromolecules

Aims and Course outcomes
At the end of this course, students will

- have gained an understanding of the characteristics that influence the relationship between molecular structure and biological activity
- be able to use and critically evaluate results achieved from structure determination of proteins and drug-related compounds
- be able to use and critically evaluate results obtained with modern computer-based methods for structure-activity analysis of biologically active compounds
- have gained knowledge of the principles and methods used for rational discovery and development of new or better drugs.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises

Examiners:
Course Teacher(s) without external examiner

Teaching tools:
PC
LCD
table
flip chart

Permitted aids:
All written and approved pocket calculator

The relationship between theoretical and practical study: 1:1

Recommended Literature

- Molecular Modeling, H.-D. Höltje, W. Sippl, D. Rognan, G. Folkers, 3. ed, 2008, Wiley-VCH
- Supplementary notes (notes with additional information on methods used – to be downloaded from course homepage)

Pharmaceutical Formulation of Peptides and Proteins (E)

Short description:
With focus on (pre-)formulation, the course describes the development of peptide- and protein-based drugs from production.

Aims and Course outcomes

At the end of the course, students are expected to:

1. Explain the principles of formulation for peptides and proteins
2. Outline the options for the formulation of peptides and proteins.
3. Explain the most important methods for characterizing drugs based on peptides and proteins.
4. Discuss and elaborate on the scientific literature in the field of peptide/protein formulation.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:
PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature

- Pharmaceutical formulation of peptides and proteins, S. Frokjaer and L. Hovgaard, 2000, Taylor & Francis
- Selected articles and hand-outs available on the course homepage

Statistical Design and Analysis of Experiments (E)

Short description:
To introduce a general statistical approach to the design of laboratory and similar experiments and to analyse the resulting data. Along with the statistical and methodological content of the course, a number of concrete and frequently used pharmaceutical applications (designed experiments) are presented. Examples are clinical trials (including e.g. crossover and repeated measures designs), toxicity testing, bio-equivalence analyses, assay validation, design and analysis of epidemiological surveys, etc. Regarding the statistical

design of experiments, the main objective is to assure the accuracy and precision of the data so that reliable and reproducible conclusions can be drawn concerning the relations being studied.

Aims and Course outcomes

After completing the course, the student is expected to know how to design relevant experimental work to support the lifecycle phases of a new pharmaceutical product: discovery, development, production and quality control. The student can judge the necessary amount of experimentation, take into account practical restrictions and anticipate and prevent/mitigate sources of the types of bias often encountered during these phases. The student will learn to carry out statistical analysis of data obtained from a given experimental design, most often using variance and regression analysis techniques. The student will also learn to present and interpret the results obtained.
The student will become familiar with using and understanding output from modern statistical computer software.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) and external examiner

Teaching tools:

PC
LCD
table
flip chart

Permitted aids:

All written and approved pocket calculator

The relationship between theoretical and practical study: 1:1

Recommended Literature

- Design and Analysis of Experiments, D. C. Montgomery, 7. ed., 2009.
- Lecture notes are available from the course homepage.

Advanced Spectroscopy (E)

Short description:

Spectroscopic methods of structure elucidation and characterization are of profound importance in connection with organic synthesis, work with pharmaceuticals and their metabolites, with biochemicals, natural products, foods and food additives, endogenous and environmental toxins, biotechnology products, etc. Spectroscopic methods are therefore of interest for students, researchers, and other personnel working in many areas of pharmaceutical, natural, life and health sciences.

The course introduces students to understanding and practical applications of modern spectroscopic techniques. The course focuses on methods used to determine structures of organic compounds, comprising determination of atomic composition, atom connectivities, and relative stereochemistry, including data processing and analysis with spectroscopic software.

Aims and Course outcomes

Students will learn to use advanced NMR spectroscopic techniques and mass spectrometry for structure elucidation of complex organic compounds, including spectra assignment. At the end of the course, students should be able to:

- Interpret first order coupling patterns as well as simple second order coupling patterns in ^{1}H NMR spectra
- Predict and interpret ^{1}H and ^{13}C NMR chemical shift values for small to medium size organic molecules and use them to solve structural problems
- Interpret homo- and hetero nuclear 2-D NMR experiments such as COSY, NOESY/ROESY, HSQC and HMBC to deduce structural fragments and their connections
- Explain fragmentation patterns in EI mass spectra and to be familiar with other techniques/ionization forms of mass spectrometry.

In addition, students are expected to be able to select suitable spectroscopic experiments, alone or in combination, to solve various structural and stereochemical problems, including sample preparation, to perform independent structure elucidation work with a complex molecule based on a set of spectra, and to communicate the results using standard spectroscopic terminology.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:

PC
LCD
table
flip chart

Permitted aids:

All aids are permitted during the examination project. Students are entitled to the confirmation of elemental composition found for their unknown compound before proceeding with the project. In addition, students are entitled to up to 30 min of individual consultation during the project period.

The relationship between theoretical and practical study: 1:1

Recommended Literature

- JH Simpson, Organic Structure Determination using 2-D NMR Spectroscopy – A Problem Based Approach, Academic Press 2008.
- Handouts, exercises and assignments prepared by the teachers are available at the course home page.

Advanced Pharmacognosy (E)

Short description:
The course aims to give students insight into the advantage of using ethnopharmacology and chemotaxonomy as a background for screening plants for potential drugs. Students will have the opportunity for a high level study of a biological topic in depth, where different elements will be combined in an interdisciplinary course with secondary plant metabolites as the common denominator. The course provides practical knowledge of phytochemical methods and some of the bioassays used to test traditional medicine for pharmacological activity.

Aims and Course outcomes

At the end of the course, students should have:

- Have acquired knowledge about secondary metabolites in the plant kingdom and an understanding of their distribution, possible function in the plant, and pharmacological effects.
- Have acquired understanding of ethnopharmacological issues and working methods in order to evaluate the quality of ethnopharmacological studies and be able to plan and conduct their own.
- Be able to carry out *in vitro* screening of plant extracts.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:
PC
LCD
table
flip chart

Permitted aids:

- Permitted aids in MC-tests: All written and approved pocket calculator
- Permitted aids for literature project: All

The relationship between theoretical and practical study: 1:1

Recommended Literature
Selected scientific articles and practical laboratory manual prepared by subject teachers are available on the course home page.

Toxicology (E)

Short description:
The main objectives of the course is to introduce fundamentals and key methods in human-, and occupational toxicology, and to provide an overview of different approaches for acquiring data that may be applied in risk evaluation of pharmaceuticals and chemical pollutants to humans and the environment. The course consists of a number of lectures and a written assignment. The course is recommended for students who upon completion of their studies will be employed in sectors dealing with pharmaceuticals, health risks,

environmental issues, such as public inspection, public health, environmental consulting, medical industry and the bioprocessing industries.

Aims and Course outcomes

Upon completion of the course, the student will be able to:

Knowledge:

- Describe toxicological mode of actions for most important groups of chemical substances to humans and environmental species.
- Define the most vulnerable target organ(s) or organism(s) for most important group of xenobiotics.
- Demonstrate knowledge on safety toxicology, and extrapolation from animal to human.
- Understand the use of physico-chemical parameters of compounds to predict toxicity, bioaccumulation and biomagnification
- Assess both acute and chronical toxicity data and evaluate different types of dose-response relationships including effects of mixtures of compounds with similar mode of action.
- Quantify a dose or an exposure of a chemical and be able to predict the most important exposure routes to humans and environment and exposure due to occupation.
- Suggest how to diminish an exposure of chemical in both human, environmental and occupational toxicology (practical management).
- Classify chemicals and xenobiotics (Tx, T, Xn, C and Xi).

Skills:

- Transfer math concepts to solve 1st-order linear differential-integral equations, manipulate log relationships, convert between dimensional systems of units.
- Utilise relevant software for dose-responds relationships and problem solving (e.g. EPI-Win, Chem-Draw, Excel, R).
- Have knowledge on simple in-vitro human toxicological tests and models.
- Report scientific results as a risk assessment report.

Competencies:

- Integrate principles from chemistry, physics, biology, biochemistry and physiology with mass and energy balances to develop and solve simple toxicological questions.
- Apply simplified assumptions and estimate model and design parameters in the face of biological variability and uncertainty in measurement and prediction.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) and external examiner

Teaching tools:

PC
LCD
table
flip chart

Permitted aids:
All written, approved pocket calculator and molecular model building set.

The relationship between theoretical and practical study: 1:1

Recommended Literature

- John Timbrell 'Principles of Biochemical Toxicology', 4rd edition, Taylor & september 2009
- Different notes and scientific papers provided on the course homepage (Albanian/English)

Toxicology and Ecotoxicology (E)

Short description:

The main objectives of the course is to introduce fundamentals and key methods in human-, eco- and occupational toxicology, and to provide an overview of different approaches for determining data that may be applied in risk evaluation of chemical pollutants to humans and the environment. The course consists of a number of lectures and a practical laboratory course of approximately 20 hours. The course is recommended for students who upon completion of their studies will be employed in sectors dealing with environmental issues, such as public inspection, public health, environmental consulting, medical industry and the bioprocessing industries.

Aims and Course outcomes

Upon completion of the course, the student will be able to:
Knowledge:

- Describe toxicological mode of actions for most important groups of chemical substances to humans and environmental species.
- Define the most vulnerable target organ(s) or organism(s) for most important group of xenobiotics.
- Demonstrate knowledge on safety toxicology, and extrapolation from animal to human, and from one trophic level in the environment to another
- Understand the use of physico-chemical parameters of compounds to predict toxicity, bioaccumulation and biomagnification
- Assess both acute and chronical toxicity data and evaluate different types of dose-response relationships including effects of mixtures of compounds with similar mode of action.
- Quantify a dose or an exposure of a chemical and be able to predict the most important exposure routes to humans and environment and exposure due to occupation.
- Suggest how to diminish an exposure of chemical in both human, environmental and occupational toxicology (practical management).
- Classify chemicals and xenobiotics (Tx, T, Xn, C and Xi).

Skills:

- Transfer math concepts to solve 1st-order linear differential-integral equations, manipulate log relationships, convert between dimensional systems of units
- Utilise relevant software for dose-responds relationships and problem solving(e.g. EPI-Win, Chem-Draw, Excel, R).
- Perform simple in-vitro human toxicological and ecotoxicological laboratory tests and models
- Report laboratory results as research manuscript

Competencies:

- Integrate principles from chemistry, physics, biology, biochemistry and ecology with mass and energy balances to develop and solve simple toxicological questions
- Apply simplified assumptions and estimate model and design parameters in the face of biological variability and uncertainty in measurement and prediction

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises
Examiners:
Course Teacher(s) and external examiner

Teaching tools:
PC
LCD
table
flip chart
Permitted aids:
All written, approved pocket calculator and molecular model building set.

The relationship between theoretical and practical study: 1:1

Recommended Literature

- John Timbrell 'Principles of Biochemical Toxicology', 3rd edition, Taylor & Francis Inc., 2000 (PBT) - new edition september 2009!
- Steve P Hopkin, Principles of Ecotoxicology, Third Edition, Taylor and Francis Inc. 2005
- Scientific and technical articles and handouts will be provided at cost.

Pharmaceutical Preformulation - Profiling Drug Substances for the Biomedical Sciences (E)

Short description:
To give students:

- insight into the methods used for physicochemical characterization of drug substances and instability studies as well as interpretation and assessment of experimental data.
- understanding of the importance of pharmaceutical profiling of drug substances in relation to selecting formulation strategies and drug administration route.

Aims and Course outcomes
At the end of the course students should be able to:

- understand the importance of basic physicochemical and stability properties of drug substances in drug development.
- calculate/predict basic prefomulation parameters.

- account for the advantages and limitations of methods used in pharmaceutical profiling of drug substances.
- design experiments related to physicochemical characterization and stability studies of drug substances.
- assess experimental data obtained in preformulation studies.
- discuss the selection of drug candidates and design of dosage forms on the basis of their stability and measured physical chemical properties.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises
Examiners:
Course Teacher(s) without external examiner

Teaching tools:
PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature
Selected scientific articles, chapters from relevant books and supplementary notes.

Immunological and Microbiological Methods in Quality Control of Medicines (E)

Short description:
To give students the opportunity to learn, evaluate and execute microbiological and immunological methods in research and quality control of medicines. The methods described in Ph.Eur. and other regulatory authorities are addressed.

Aims and Course outcomes

General abilities: The students will acquire practical and theoretical abilities and skills in microbiological and immunological methods used for research and quality control of medicines. The methods are applicable in the pharmaceutical industry and in academia.

Specific abilities: By the end of the course, the students will have acquired the ability to:

- design in vitro assays for evaluation of immumodulation, including choosing the proper model system and assay conditions
- design an experiment on the basis of original literature to illustrate immunomodulation
- analyse and evaluate the results of different in vitro techniques
- identify analytical problems in cell based assays
- calculate and interpret data (dose-response relationships)
- use a graphics program (SigmaPlot) to show results graphically

- evaluate scientific literature within the topics covered by the course, as well as to search scientific literature in databases (Medline and others)
- conduct Quality Control as described by Regulatory Authorities
- conduct experiments using in vitro techniques like cell lines, immunoassays and enzymatic assays
- detect and measure endotoxin and other pyrogens in pharmaceutical formulations.

Specific practical skills: By the end of the course, the students will have acquired sufficient skills to be able to:

- work with cell lines (monocytes and granulocytes) under aseptic conditions
- measure cytokines in cell cultures using immunoassays (ELISA/DELFIA technique)
- perform Limulus (LAL) test and validation of LAL test
- perform Monocyte activation test (MAT) and validation of MAT
- solve issues of interference in enzymatic and cellular assays
- measure ATP in samples
- measure reactive oxygen species in cell cultures
- perform ultrafiltration
- execute total viable count

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:

PC
LCD
table
flip chart

Permitted aids:

- Permitted aids for exam preparation: All written and approved pocket calculator
- Permitted aids at the actual exam: Own notes from exam preparation

The relationship between theoretical and practical study: 1:1

Recommended Literature

Scientific articles and instructions for laboratory exercises

Pharmaceutical Policy, Economics and Ethics (E)

Short description:

The purpose of the course is based on the increased need for priorities of society in healthcare that enable students to be critical and analytical approach to problems in the pharmaceutical field with aspects of economics, politics and ethics in order to contribute to the optimal solution of the current problems in terms of adequacy drug development and use.

Aims and Course outcomes
Tuition strives to students at the end of the course must:

able to explain the different actors often divergent interests of specific problems in the field of medicines and evaluate the actions and statements in light of those identified interests
be able to relate background knowledge in the field of medicines including the structure of health care and regulation of drug development and use of the importance of economic, political and ethical aspects of issues in the field of medicines
be able to choose appropriately between different economic models to make appropriate calculations within the economic problems in the pharmaceutical field
be able to justify the relevance of the use of specific economic, political or ethical tools within issues in the pharmaceutical field
be able to apply specific tools of economics, politics and ethics on issues within the pharmaceutical field in a satisfactory manner
be able to explain and justify the appropriate decisions, taken together, should be made on the basis of analyzes of economic, political, and ethical aspects of issues in the pharmaceutical field.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises

Examiners:
Teacher (s) without external examiner

Teaching tools:
PC
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table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature
Gisela Kobelt: Health Economics. An Introduction to Economic Evaluation, Office of Health Economics. London, 2002, pages 131
Frederik Voetman Christiansen: Rudimentary pharmaceutical ethics (uploaded to Absalon)
Frederik Voetman Christiansen: Notice of ethics and technology - an extension to Rudimentary pharmaceutical ethics (uploaded to Absalon)
Various literature in the form of reports, articles etc.. and references to web sites (abandoned Absalon)

Applied Drug Metabolism (E)

Short description:

To give students insight into how drugs are metabolized in the body. The possible metabolic paths of drugs and the enzymes involved are discussed, so that students can propose probable metabolic pathways for the given drugs. Students must also learn about original literature and its underlying thought processes and about methods used in metabolism studies such as in vitro and in vivo test models. Students must learn about, the basic requirements to analytical methods, so that they are able to plan metabolism studies and results and understand their clinical and toxicological relevance. Therefore the course is part of the general educational objective to impart expertise in planning and conducting chemical, pharmacological and pharmaceutical development, drug production and quality assurance of drugs and active pharmaceutical substances. The course contributes to general objectives about information and advice to health care personnel and the general population.

Aims and Course outcomes

At the end of the course, students are expected to:

- know about phase 1 and phase 2 metabolic processes
- propose probable metabolic pathways for selected functional groups or drug groups
- know in which cell compartments and in which organs metabolism takes place
- be able to describe the enzyme systems the organism uses to metabolize drugs
- know about the function and significance of uptake and efflux transporters
- know how to use *in vitro* metabolism models
- know how to use *in vivo* metabolism models
- know about the analytical chemical methods used
- on the basis of the above knowledge be able to propose suitable *in vivo* and *in vitro* models and relevant analytical chemical methods for conducting drug metabolism studies
- understand the significance of drug metabolism for the development of new drugs.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:
Course Teacher(s) without external examiner

Teaching tools:

PC
LCD
table
flip chart

Permitted aids:
All written and approved pocket calculator

The relationship between theoretical and practical study: 1:1

Recommended Literature

- Drug Metabolism in Drug Design and Drug Development, D. Zhang, M. Zhu and W.G. Humphreys (eds.), Wiley-Interscience (John Wiley & Sons, Inc.), Hoboken, New Jersey, USA, 2008, ISBN 978-0-471-73313-3.
- Other course materials include relevant guidelines from the FDA and EMEA (ICH), articles relevant for lectures and instructions for laboratory exercises. These materials are available from the course homepage.

Advanced Drug Delivery (E)

Short description:
To give students a theoretical and experimental background for evaluating selected, recently developed advanced drug delivery principles as well as the ability to critically evaluate the relevant literature. Emphasis is also on presenting and discussing scientific literature.

Aims and Course outcomes

At the end of the course, students should be able to:

1. give an account of selected advanced drug delivery systems e.g. liposomes, SMEDDS, nanoparticles and stabilised amorphous forms, including their areas of application
2. give an account of important physiological mechanisms and kinetics related to ADME, as well as methods used to characterize ADME, *in vitro*and *in vivo*
3. evaluate scientific literature related to advanced drug delivery
4. demonstrate thorough understanding of the laboratory experiments included in the course.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:
PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature
Scientific articles available from the course website.

Independent Elective Study (including bachelor project) (E)

Short description:
The course aim is to give students the opportunity to independently plan and carry out an individual study motivated by academic and personal interests and in cooperation with a teacher from the Faculty of Pharmaceutical Sciences. The individualised study unit can be conducted in Denmark or abroad. The following description is a framework description that can be used in case of:

- master's students taking individualised elective courses,

- projects carried out as part of a pharmaceutically relevant bachelor's project different from the bachelor's project in pharmacy (= an "alternative" bachelor's project),
- project-oriented courses as part of the master's programme in pharmaceutical sciences, in which the student is stationed at a pharmaceutically relevant company, including a university, in Denmark or abroad
- projects for Danish and foreign students who are not enrolled on a Faculty programme but who carry out a project with a supervisor from the Faculty.

Aims and Course outcomes

At the end of the course, students should have increased:

- Their academic insight and knowledge
- Their independence with regard to planning and carrying out a large project.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Course Teacher(s) without external examiner

Teaching tools:

PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature

Pharmacotherapy (E)

Short description:

To give students insight into clinical disease states and knowledge of the most important types of disease and their underlying pathophysiology, and to provide insight into the principles of diagnostics and prognosis. Furthermore to provide students with solid knowledge of the principles underlying rational, evidence-based pharmacotherapy, including the benefits and risks of treatment with various drug groups.

Aims and Course outcomes

At the end of the course, students are expected:

1. To be familiar with the most common and important types of disease and their pathophysiology
2. To be able to propose an optimal course of drug treatment on the basis of a patient's disease, clinical condition and paraclinical data
3. To be able to gather systematically the necessary information about drugs and treatment options - via national treatment guidelines, the Cochran Library, and national and international databases on adverse effects and interactions – in order to evaluate optimal and rational pharmacotherapy

4. To be able to advise doctors, nurses and patients in a knowledgeable manner
5. To be able to present a patient's course of illness and treatment to colleagues.

Teaching and learning methods:
Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing
Writen exam
Active participation in the practical excercises
Examiners:
Course Teacher(s) and external examiner

Teaching tools:
PC
LCD
table
flip chart
Permitted aids:
None, **not even** pocket calculators
Special conditions:
Out of four medical histories presented, each student selects three to solve.

The relationship between theoretical and practical study: 1:1

Recommended Literature

- Clinical Pharmacy and Therapeutics Ed. Roger Walker and Whittlesea. Churchill Livingstone, latest edition.
- Selected publications from the Department of Rational Pharmacotherapy (www.irf.dk) and NIH (www.nice.org.uk).

Clinical Pharmacy (E)

Short description:
The purpose of the study unit is to provide students with insight into patients' disease situation so that they can assess the medical treatment and on this basis provide professional guidance to the patient, the doctor and others involved in the patient's medical treatment Study Unit aim is also to provide students with sufficient clinical background to operate in the pharmaceutical industry within the pharmaceutical and clinical areas, as well as to cooperate with doctors and nurses in primary and secondary care.

Aims and Course outcomes

The aim is that the students at the end of this study unit can:

use subjects pathology, physiology, pharmacology and pharmacy in the practical use of drugs in patient care.
describe diseases, treatments, care of patients, the use of laboratory data and on this basis, evaluate the medical treatment.
gain insight and understanding for cooperation between clinical specialties (f.ex intensive therapy and clinical microbiology) and cooperation between the various health professions
participate in decisions regarding patients' drug therapy and assess the route of administration and dosage regimen.
advise patients and health care professionals regarding the optimal use of medicines
discuss the drafting traits and physiological influences upon drug substance tax rate, absorption and efficacy.
discuss the formulation of law in relation to the drug's clinical use.

Teaching and learning methods:

Learning objectives will be met through lectures, and practical excercises

Assessment methods and criteria for passing

Writen exam
Active participation in the practical excercises

Examiners:

Teacher (s) without external examiner

Teaching tools:

PC
LCD
table
flip chart

The relationship between theoretical and practical study: 1:1

Recommended Literature

R. Walker & C. Edwards, Clinical Pharmacy and Therapeutics, 4rd ed. 2007 Churchill Livingstone, ISBN-13: 9780443102851
Treatment guidelines from the IRF and medical companies' websites
Lecture Notes: Lay on the course website