

National Pirogov Memorial Medical University, Vinnytsya

«APPROVE»

Acting rector of higher education institution

 Viktoriia PETRUSHENKO

" 31 " 08 2023

«AGREED»

Head of clinical pharmacy and
clinical pharmacology department

 Sviatoslav SEMENENKO

" 31 " 08 2023

**SYLLABUS
of academic discipline**

BIOPHARMACY

Specialty	226 "Pharmacy, industrial pharmacy"
Educational level	the second (master's) level
Educational programme	EPP "Pharmacy", 2022
Academic year	2023-2024
Department	<i>Clinical pharmacy and clinical pharmacology</i>
Lecturer	Ass-prof. Inna Doroshkevych
Contact information	<i>clinpharm@vnm.edu.ua, Pirogov str, 56</i>
Syllabus compiler	Ass-prof. Inna Doroshkevych

1. Status and structure of the discipline

Discipline status	Compulsory
Discipline code in EPP/discipline place in EPP	CC 38, discipline of professional training
Course / semester	5th year (IX semesters)
The amount of discipline (the total number of hours / number of credits ECTS)	90 hours / 3,0 credit ECTS
The structure of the discipline	Lectures - 8 hours Practical classes 38 hours Independent work 44 hours In general: auditory classes – 51,1%, independent work - 48,9%
Language of study	English
Form of study	Full-time (<i>or remote full-time by order</i>)

2. Description of the discipline

Short annotation of the course, relevance.

The program of the discipline "Biopharmacy" is made according to the order of preparation of applicants of the second (master) level of education in higher medical educational institutions of Ukraine according to requirements of the credit transfer system of the educational process ECTS, the approximate curriculum of training of the second (master) level knowledge 22 "Health care" specialty 226 "Pharmacy, industrial pharmacy".

The discipline is a mandatory component of the educational and professional program "Pharmacy", the cycle of training Master of Pharmacy, designed for 3 credits, which students learn during the IX semester in the 5th year of study.

The main focus of the program is to obtain knowledge in the discipline of "Biopharmacy", the study of which is necessary for the successful mastering of disciplines. The subject area of the program is to train a specialist with a sufficient amount of theoretical knowledge and practical skills on the effects of drugs on the human body depending on various factors, both the external environment and the functional systems of the human body. The peculiarity of this subject is that with the same groups of drugs for the treatment of conditions in which they will act, differ significantly, the list of these conditions, or external and internal factors in relation to man - is the basis of the subject.

The course introduces students to some methods "in vitro" and "in vivo" to determine the influence of major variables of pharmaceutical and biological factors on the degree of release of drugs from dosage forms, their rate of absorption through histohematological barriers into the blood, bioavailability and bioequivalence. The modern requirements reflected in the state standards of Ukraine concerning preparation and use of medicines are stated.

The discipline "Biopharmacy" reflects as much as possible the individual characteristics of the patient in the process of his interaction with drugs.

Prerequisites. For successful mastering of discipline, the student needs the knowledge received in the course of studying of the following disciplines of the general preparation:

pharmacology, pharmacotherapy, medical biology, physiology and pathological physiology with the basics of pathological anatomy, microbiology, general pharmacokinetics, medical and

pharmaceutical ethics and deontology, clinical and laboratory diagnostics, which precede the study of the discipline or are studied simultaneously.

The purpose of the course and its significance for professional activities. The purpose of teaching the discipline is for students to master the theoretical and practical foundations of biopharmacy for scientific substantiation of the composition and technology of new drugs and improve existing ones using modern excipients, new technologies by increasing their effectiveness and reducing side effects on the body.

Familiarization of students with world achievements, which determine the theoretical justification of possible consequences of drug interaction in different conditions of human existence, while taking drugs, expanding their philosophical, biological understanding of the unity of man and the environment - from space to the microworld of life, understanding these complex relationships in all their diversity.

Postrequisites. Summarizes the knowledge gained by students in the study of basic disciplines: pharmaceutical technology of drugs, industrial technology of drugs, pharmacology, pharmacotherapy, clinical pharmacy, etc.

3. Learning outcomes.

After successful study of the discipline the applicant will be able to:

- own and use the necessary regulatory documentation and reference literature;
- determine and justify the method of preparation, route of administration and features of the use of drugs;
- standardize the dosage form according to pharmaceutical (technological and analytical) parameters and know the requirements for safety and efficacy of drugs;
- predict the possible interaction of drugs with their simultaneous appointment;
- be able to determine the pharmaceutical and bioavailability of drugs by different methods;
- to build curves of dynamics of release of the investigated drugs depending on various biopharmaceutical factors;
- calculate bioavailability, elimination constants and half-life of substances from different dosage forms.

4. Content and logistic of the discipline

<i>Content module 1.</i> <i>Biopharmaceutical aspects of drugs</i>	IX semester 90h	Lectures № 1-4 Practical class № 1-18 Independent students work № 1-18
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The course includes 18 topics, which are divided into 1 thematic module.

Content module 1. Biopharmaceutical aspects of drugs

Topic 1. Introduction to biopharmacy, basic concepts and terms. Pharmaceutical factors of drugs

Topic 2. The impact of routes of administration on the bioavailability of drugs.

Topic 3. The impact of routes of administration on the bioavailability of drugs. Features of drug use in oral, rectal routes of administration, on the skin and mucous membranes.

Topic 4. Features of the use of drugs in aerosol delivery routes.

- Topic 5. Types of drug interactions - pharmaceutical, pharmacokinetic, pharmacodynamic. Influence of drug interaction on their bioavailability.
- Topic 6. Combined drugs and principles of their application
- Topic 7. Interaction of drugs with food
- Topic 8. The impact of diseases of internal organs on the pharmacokinetics of drugs
- Topic 9. The influence of age-related changes in the human body on the pharmacokinetics and pharmacodynamics of drugs
- Topic 10. Features of the use of drugs during pregnancy
- Topic 11. Features of the use of drugs during lactation
- Topic 12. Features of the use of drugs in childhood
- Topic 13. Features of drug pharmacokinetics in overweight
- Topic 14. The effect of alcohol on the pharmacokinetics and pharmacodynamics of drugs
- Topic 15. The effect of smoking on the pharmacokinetics and pharmacodynamics of drugs
- Topic 16. The impact of drug addiction on the pharmacokinetics and pharmacodynamics of drugs
- Topic 17. The influence of biorhythms of the human body on the effectiveness of drugs
- Topic 18. Interaction of drugs with phytopreparations

The topics of the lecture course reveal the problematic issues of the relevant sections of biopharmacy.

Practical classes provide a theoretical justification of the main issues of the topic and the acquisition of the following practical skills:

- determine and justify the method of preparation, route of administration and features of the use of drugs;
- know the requirements for safety and efficacy of drugs;
- predict the possible interaction of drugs with their simultaneous appointment;
- be able to determine the pharmaceutical and bioavailability of drugs by different methods;
- to build curves of dynamics of release of the investigated drugs depending on various biopharmaceutical factors;
- calculate bioavailability, elimination constants and half-life of substances from different dosage forms.

Thematic plans of lectures, calendar plans of practical classes, volume and directions of individual work are published on the website of the department.

The route for obtaining materials: Department of Clinical Pharmacy and Clinical Pharmacology / Student / Full-time / Pharmacy, industrial pharmacy / 5th year / Educational and methodical materials / or by the link <https://www.vnmu.edu.ua/> Department of Clinical Pharmacy and Clinical Pharmacology #. Access to materials is provided from the student's corporate account s000XXX@vnmu.edu.ua.

5. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: oral or written survey, testing, electronic survey, solving situational problems.
Final control of the discipline - differential credit	Methods: testing, oral questioning (according to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmu.edu.ua/General information))

Learning success diagnostic tools	Theoretical questions, tests, clinically-oriented situational tasks.
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6. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in VNMU named after M.I. Pirogov (link link <https://www.vnmv.edu.ua/General> information)

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Final control of the discipline	Final differential credit test grade: 71-80 points - "excellent" 61-70 points - "good" 50-60 points - "satisfactory" Less than 50 points - "unsatisfactory" / did not pass
Discipline assessments:	Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline Final control - from 50 to 80 points: 40% of the grade for the discipline Individual work - from 1 to 12 points From 122 to 200 points in total.

Discipline Score Scale: National and ECTS

The sum of grades for all types of educational activities	Score ECTS	Score on a national scale	
		For exam, course project (work), practice	for credit test
180-200	A	excellent	credited
170-179,9	B	good	
160-169,9	C		
141-159,9	D	satisfactory	
122-140,99	E	satisfactory	credited
121-61	FX	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
1-60	F	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

Criteria for student knowledge assessment

Evaluation of the oral / written answer during the current control

The grade **"excellent"** is given to a student who knows the features of the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects, interaction of different groups of drugs. Methods of their appointment, methods for assessing the effectiveness of action, duration of

action of drugs. The choice of drugs taking into account the above criteria and the functional state of the body, sex, age of the patient. Rational combinations of therapy. Prevention and measures of immediate therapy in case of complications from treatment. The answers must be deep, meaningful and specific. The student correctly, clearly, logically and fully answers all standardized questions of the current topic, is able to summarize the material.

The grade **"good"** is given to a student who knows the features of the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects, interaction of different groups of drugs. Methods of their appointment, methods of evaluating the effectiveness of action. The choice of drugs taking into account the above criteria and the functional state of the body, sex, age of the patient. Prevention and measures of immediate therapy in case of complications from treatment. The answers are quite meaningful and specific. The student correctly and essentially answers the standardized questions of the current topic. Has the necessary practical skills and abilities in excess of the required minimum.

A grade **"satisfactory"** is given to a student who knows a mandatory minimum of theoretical knowledge and practical skills - to know the representatives of groups of drugs, features of pharmacokinetics, pharmacodynamics, side effects of drugs, methods of administration. The answers are incomplete, the knowledge is superficial.

The grade **"unsatisfactory"** is given to a student who does not have minimum knowledge of drug toxicology, does not focus on pharmacokinetics, pharmacodynamics, side effects of drugs, the peculiarities of their interaction, methods of monitoring therapy and measures for immediate care in case of complications. The answers are vague, incorrect, or completely absent.

Evaluation of test tasks during the current control

The grade **"excellent"** is given to the student who at carrying out test control is allowed no more than 10% of incorrect answers (volume of correct answers 90-100%).

A grade of **"good"** is given to a student who makes no more than 20% of mistakes during the test (the amount of correct answers is 80-89%).

A grade of **"satisfactory"** is given to a student who makes mistakes in no more than 30% of test tasks (the amount of correct answers is 70.5-79%).

A grade of **"unsatisfactory"** is given to a student who correctly solves less than 70% of the test tasks in a test.

Evaluation of the implementation of situational tasks during the current control

The grade **"excellent"** is given to the student freely solves situational clinically-oriented problems of increased complexity, correctly, clearly, logically and fully answers all components of the problem.

A grade of **"good"** is given to the student who is able to solve light and medium situational clinically-oriented problems, while correctly and essentially answers most questions to the problem, correctly uses theoretical knowledge in solving practical problems.

A grade of **"satisfactory"** when solving situational problems, provides correct answers to only some questions to the problem, or the answers are incomplete.

A grade of **"unsatisfactory"** when solving situational problems, he cannot provide the correct answers to the questions to the problem. The answers are vague, incorrect, or completely absent.

Assessment of independent students work

The calculation of individual points is carried out on the basis of the Regulation of the Academic process in VNMU named after M.I. Pyrogov (link <https://www.vnmua.edu.ua/General> information).

12 points are reserved for the ISW assessment, which are accrued as follows:

12 points - added to the assessment of the discipline for a student who won a prize at the interuniversity competitions in the discipline or a prize at the Ukrainian competition of student research reports or a prize at the interuniversity / international scientific conference with the published work;

11-10 points - are added for prizes at intra-university competitions and student scientific conferences with the published work.

10 points - are added to the assessment of the discipline for participation (if the student participated but did not receive a prize) in interuniversity competitions in the discipline and interuniversity and international scientific student conferences with the published work.

8 points - are added to the assessment of the discipline for participation (if the student participated but did not receive a prize) in intra-university competitions and student scientific conferences with the availability of printed work.

6 points - are added to the assessment of the discipline for the manufacture of drugs at the departments, schemes, tables of multimedia software and videos - taking into account the importance of the work performed.

If the sum of points for ISW exceeds 12, the remaining points by the decision of the cathedral meeting can be added as a bonus points to the score on the final modul control.

Students' independent work on a topic that is included in the thematic plan is assessed during the current control of the topic in the relevant lesson.

Assessment of the final modul control

A grade "**Excellent**" are awarded to a student who was able to give a long answer to 3 theoretical questions and provided correct answers to test questions in the amount of at least 90%, has a thorough knowledge of clinical pharmacology and can clearly cover the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects and interaction of different groups of drugs; knows the methods of their appointment, methods of assessing the effectiveness of action, duration of action of drugs, measures of immediate therapy in case of complications from treatment, can choose drugs taking into account the functional state of the body, sex, age of the patient.

A grade "**Good**" are awarded to a student who was able to give a complete answer to 3 theoretical questions and provided correct answers to test questions in the amount of at least 80%, has a thorough knowledge of clinical pharmacology and can clearly cover the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects. actions and interactions of different groups of drugs; knows the methods of their appointment, methods of assessing the effectiveness of action, duration of action of drugs, measures of immediate therapy in case of complications from treatment, but made minor errors in the coverage of one of these sections.

A grade of "**satisfactory**" are awarded to a student who was able to give a partial answer to 3 theoretical questions and provided correct answers to test questions in the amount of at least 70%, has basic knowledge of clinical pharmacology and can partially cover the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects. actions and interactions of different groups of drugs; methods of appointment, methods of assessing the effectiveness of action, duration of action of drugs, measures of immediate therapy in case of complications from treatment, while making minor errors in the coverage of one of these sections.

The grade "**Unsatisfactory**" are awarded to a student who failed to answer at least one of the theoretical questions and provided correct answers to test questions in the amount of less than 70%, has basic knowledge of clinical pharmacology, has an idea of the content of the main sections. Questions concerning the mechanism of action, classification, pharmacokinetics, pharmacodynamics, side effects and interaction of different groups of drugs; methods of appointment, methods of assessing the effectiveness of action, duration of action of drugs, measures of immediate therapy in case of complications from treatment responds unconsciously, making mistakes.

7. Policy of discipline / course

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified tutoring during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student-centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in VNMU named after M.I.Pirogov and the principles of academic integrity (link <https://www.vnmu.edu.ua/General> information).

Adherence to the rules of VNMU, safety techniques in practical classes.

Safety instruction is given at the first practical session by the teacher.

ALGORITHM OF ACTION for education applicants, scientific and pedagogical workers of National Pirogov Memorial Medical University, Vinnytsia throughout the operation of the «AIR ALARM» during working hours

Before the first class starts, teacher must explain extensively how to get to the shelter.

The shelters of the Department of Clinical Pharmacy and Clinical Pharmacology are located at the ground floor of morphological building of the VNMU, the cellar-shelter of the hostel №3, the basement-shelter of the University Clinic of the VNMU, the basement - shelters of VCCH №.3 in accordance with the base for conducting practical classes.

In case when the alarm signal sounds during the classes «AIR RAID! EVERYONE GOES TO THE NEAREST SHELTER» it is necessary to: Stop the class immediately; after the teacher announces: «Pack your things, quickly go to the shelter», quickly pack things and get ready to leave; make sure that there is no one left in the auditorium; turn off the light, close the door (mainly performed by the teacher); follow the last student to move to the shelter (performed by the teacher); stay at the shelter until the signal «CAUTION! ALL-CLEAR!» (two short sirens announcing same as for the sounding of the air alarm); after the signal «CAUTION! ALL-CLEAR!» return to the classroom to continue the lesson; if the signal «CAUTION! ALL-CLEAR!» do not occur before the end of the class, the education applicants should stay at the shelter until the signal «CAUTION! ALL-CLEAR!»; in case when the alarm signal «AIR RAID! EVERYONE GOES TO THE NEAREST SHELTER» sounds before the start of the class and the applicants arrive to the department base, the applicants must immediately go to the nearest shelter (QR code with a link to the map of the shelters of Vinnytsia city are sited at every public transport stop).

Requirements for preparation for practical classes.

The student must be prepared for a practical lesson, theoretically prepared for the topic.

Student should come to a class on time, without delay. A student who is more than 10 minutes late for class is not allowed to the last and must work it in the prescribed manner.

In practical classes, the student must be dressed in a medical gown.

When discussing theoretical issues, students should demonstrate tolerance, courtesy and respect for their colleagues and the teacher.

Usage of mobile phones and other electronic devices.

The use of mobile phones and other electronic devices during the lesson is allowed only at the instruction of the teacher.

Academic integrity. When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of VNMU named after M.I. Pirogov (link: <https://www.vnmu.edu.ua/General> information)/ Code of Academic Integrity). In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2" and must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

Missed classes. Missed classes are working out in the manner prescribed by Regulations of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmu.edu.ua/General> information) at the time of work out schedule (published on the website of the department <https://www.vnmu.edu.ua/> Department of Microbiology #) to the teacher on duty. To work out missed lesson student must provide a completed workbook protocol on the relevant topic, take a test and answer questions in writing or orally to the topic of the lesson.

The procedure for admission to the discipline final control is given in the Regulation of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmu.edu.ua/General> information). Students who do not have missed practical classes and lectures and received an average traditional grade of at least "3" are allowed to final control.

Additional points. Individual points in the discipline that student can receive for individual work, is determined by the results of his individual work according to Regulation of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmu.edu.ua/General> information) and policy of the course.

Conflict resolution. In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, student should submit his / her claims to the teacher. If the issue is not resolved, the student has a right to apply to the head of the department according to Complaints Consideration Procedure (<https://www.vnmu.edu.ua/> General information / Basic documents).

Politics in terms of remote learning. Distance learning regulated by the Regulations of the elements of remote learning in VNMU named after Pirogov M.I. (<https://www.vnmu.edu.ua/> General information). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department (<https://www.vnmu.edu.ua/> Department of Clinical Pharmacy and Clinical Pharmacology/Student or <https://www.vnmu.edu.ua/Department of of Clinical Pharmacy and Clinical Pharmacology / News>).

Feedback from teachers is via messengers, e-mail or on the Microsoft Teams platform (at the choice of the teacher) during working hours.

8. Educational resources.

Educational and methodological support of the discipline is published on the website of the department (<https://www.vnmu.edu.ua/> Department of Clinical Pharmacy and Clinical Pharmacology/ To students).

Recommended base reading:

1. V. Bobyrov. Pharmacology: textbook / V.Bobyrov, T.Devyatkina, O.Vazhnicha, V.Khristyuk. - 3rd ml., updated - Vinnitsya : Nova Knyha, 2015. -520 p.: il.
2. Brunton L.L., Chabner B.A., Knollmann B.C. Goodman and Gilman's The Pharmacological Basis of Therapeutics (12-th Edition).-2010.
3. Essentials of medical pharmacology / edited by Tripathi KD. - 6th edition. – New Delhi, 2010. – 940 p.
4. Handbook of Drug Interactions: a clinical and forensic guide. - Edited by A. Mozayani, H. County, L.P. Raymon -2004.-662 p.
5. H. Lüllmann, A. Ziegler et al. Color Atlas of Pharmacology.-2000.-662 p.
6. Katzung B.G., Masters S.B., Trevor A.J. Basic & Clinical Pharmacology (14-th Edition).-2018.- 1547 p.
7. Pharmacology - Cito!: Textbook II Edited by S.M. Drogozov. - Kharkiv, 2016. -192 p.
8. Pharmacology at your palms: reference book / Drogozov S.M., Kutsenko T.A. - Kharkiv: Nphall, 2016.-80 p.
9. Pharmacology / [edited by] Karen Whalen ; collaborating editors, Richard Finkel, Thomas A. Panavelil. – Sixth edition. – 2015. (Lippincott illustrated reviews)
10. Rational use of medicines: progress in implementing the WHO medicines strategy Report by the Secretariat, EB118/6, 11 May 2006, [Електронний ресурс].–Режим доступу: [who.int/gb/ebwha/pdf_files/EB118/B118_6-en.pdf/](http://who.int/gb/ebwha/pdf_files/EB118/B118_6-en.pdf)
11. Websites PubMed, MEDLINE, MD Consult, UptoDate, Clinical Evidence etc.
12. The European Association for Clinical Pharmacology and Therapeutics (EACPT) <http://www.eacpt.org>
13. Drug interactions resource: <http://medicine.iupui.edu/flockart/>

Recommended additional reading:

1. Pharmacology at your palms: reference book / Drogozov S.M., Kutsenko T.A. - Kharkiv: Nphall, 2016, 80 p.

Electronic resources:

1. Deartment website – <http://vnmu.edu.ua/>
2. Libraire website - <http://library.vsmu.edu.ua/>
3. State Register of Medicines www.moz.gov.ua
4. Unified patient management protocols www.moz.gov.ua
5. Australian Bulletin of Adverse Reactions.<http://www.tga.health.gov.au/adr/aadrb.htm>.
6. British Monthly Drug Safety Bulletin <http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>.
7. Lectures for postgraduate education "Principles of Clinical Pharmacology" of the Clinical Center of the National Institutes of Health. <http://www.cc.nih.gov/researchers/training/principles.shtml>.
8. Interregional Society of Evidence-Based Medicine: <http://www.osdm.org/index.php>
9. Bulletin of evidence-based medicine: <http://www.evidence-update.ru>
10. European Society of Clinical Pharmacologists and Pharmacotherapists: <http://www.eacpt.org>
11. Resource on pharmacogenetics. <http://www.pharmgkb.org/>.

12. On-line registration of adverse drug reactions on the FDA website.
<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.
13. Resource for drug interaction: <http://medicine.iupui.edu/flockart/>
14. Working group on pharmacotherapy of the European Society of Cardiology
<https://www.escardio.org/>.

Consultations are held twice a week according to the consultation schedule.

9. The timetable and distribution of groups with assigned teachers are published on the web page of the department (<https://www.vnmua.edu.ua/> Clinical pharmacy and clinical pharmacology department/ For students).

10. Questions to the final discipline control (credit) are published on the web page of the department (<https://www.vnmua.edu.ua/> Clinical pharmacy and clinical pharmacology department/ For students).

The syllabus of the discipline "Biopharmacy" was discussed and approved at the meeting of the clinical pharmacy and clinical pharmacology department (record № 1, dated 29.08.2023)

Responsible for academic discipline _____



ass. prof. of HEI Inna DOROSHKEVYCH

Acting head of the department _____



ass. prof. of HEI Sviatoslav SEMENENKO