Federal State Autonomous Educational Institution of Higher Education
«Peoples' Friendship University of Russia»

the Shared Research and Educational Center

THE WORKING PROGRAM OF THE DISCIPLINE

Name of the discipline:

Research and Anticipating the effectiveness of drugs **(in vivo, in vitro, in silico) /**
Изучение и прогнозирование эффективности лекарственных препаратов (in vivo, in vitro, in silico)

Recommended for (field/ specialty):

33.06.01 Pharmacy

The direction of the program:

Pharmaceutical technology (in collaboration with the University of Basel)

2021

1. Goals and objectives of the discipline:
The purpose of studying the discipline is to create and develop professional competencies in the field of Anticipating the effectiveness and safety of medicines (drugs) and related products.
To achieve this goal during the course, the following points are discussed
Tasks:
1. Teaching postgraduates to predict the effectiveness of drugs as a section of pharmaceutical development.
2. Provide graduate students with practical knowledge, skills, and capabilities in the field of methods of Anticipating drug effectiveness.

2. Place of discipline in the structure (General characteristics of the educational program):
The discipline "Research and prediction of the effectiveness of drugs" is an optional discipline studied in graduate school in the field of "Pharmacy" in the direction of Pharmaceutical technology (incorporation with the University of Basel).
To study this discipline, a graduate student must have a higher pharmaceutical education or relevant specialized training, have knowledge, skills, and abilities in the field of pharmacology, pharmaceutical technology, pharmaceutical chemistry, and pharmacognosy.
The study of the discipline is necessary to expand the knowledge of graduate students in the field of Anticipating the effectiveness of drugs in the process of pharmaceutical development and preparing them for the state final certification and defense of the dissertation work.

Table № 1

Previous and subsequent disciplines aimed at the formation of competencies.

№ п/п	Code and name of competence	Previous discipline	Subsequent disciplines (disciplines unit)
General professional competencies			
1	GPC-3: the ability and preparation to analyze, summarize and publicly present the results of scientific research.	Methodology of scientific research	Research practice, Scientific research, State final certification
2	GPC-4: preparation to implement the developed methods and techniques aimed at the rational, effective, and safe use of medicines.	Methodology of scientific research	Research practice, Scientific research, State final certification
3	OPC-5: ability and preparation to use laboratory and instrumental equipment for obtaining scientific data.	Methodology of scientific research	Research practice, Scientific research, State final certification
Professional competence			

4	PC-1: ability to do scientific research on the development and creation of innovative drugs, including the ones which are derived from medicinal plant materials	Methodology of scientific research	Research practice, Scientific research, State final certification
5	PC-2: ability for scientific research on obtaining more advanced forms of drugs with predictable pharmacokinetic characteristics based on modern technologies	Methodology of scientific research	Research practice, Scientific research, State final certification

3. Requirements for mastering the discipline:

The discipline study process aims to develop the following competencies:

- OPC-3: The ability and willingness to analyze, summary and publicly display the results of scientific research
- OPC -4: The ability to implement developed methods and techniques aimed at rational, effective and safe use of medicines
- OPC -5: The ability and willingness to use a laboratory equipment and tools to obtain scientific data
- PC-1: ability to do scientific research on the development and creation of innovative drugs, including those which are derived medicinal plant materials
- PC-2: ability for scientific research on obtaining more advanced forms of drugs with predictable pharmacokinetic characteristics based on modern technologies

As a result of studying the discipline, a graduate student must:

Know: 1 - the basics of general theoretical disciplines enough to solve professional problems.
2 – the basics of general theoretical disciplines to the extent necessary for solving professional problems.
3 – theoretical foundations of modern methods for Anticipating the effectiveness of drugs.

Be able to: 1 - operate the obtained theoretical knowledge in the process of pharmaceutical development.
2 - prepare reagents for carrying out experiments on Anticipating efficiency with the requirements of pharmacopoeias.
3 - conduct experiments to predict the effectiveness of drugs using chemical and physico-chemical methods of analysis, as well as using special software.
4 - interpret and evaluate the results of prediction experiments.
5 - conduct research on Anticipating the effectiveness of various drug forms.
6 - Use of international normative documents regulating drug development processes.

Possess: 1 - The skills of conducting scientific research on the specialization file, whether as part of a group or independently, while being aware of special means and methods for obtaining new knowledge.

2. Scope of discipline and types of educational work

3. The total workload of the discipline is 4 credit units

Type of educational work	Total hours	Courses
		2 courses
Classs (lessons) (total)	144	144
Includes :		
Lectures	40	40
Practical lessons (P3)	40	40
Seminars (S)	-	-

Laboratory work (LW)	-	-
Independent work (IW) (total)	46	46
Includes:	-	-
Course project (work)	-	-
design and graphic works	-	-
abstract	46	46
Other types of independent work		
intermediate validation (test, exam)	18, credit	18, credit
Total– hour / cred. units	144/4	144/4

4. Content of the discipline

4.1. Contents of discipline sections

№ п/п	Name of the section, topic of the academic discipline (module)	Contents of the section, topic (module)
1.	Biopharmaceutical analysis (introduction)	Determination of the concentration of medicinal substances and their metabolites in biological fluids of the human body (theoretical aspects). Study of the pharmacokinetics of drugs. Study of the bioavailability of drugs. Study of biotransformation of drugs. Establishing the range of the minimum therapeutic and toxic levels of drugs in the body. Revealing the dependence of pharmacokinetic parameters and drug concentration on the state of the human body
2.	Questions of biopharmaceutical analysis	Features of the extraction of medicinal substances from biomaterials. Concentration characteristics of medicinal substances extracted from biomaterials to achieve the required limits for their detection and quantification. Methods for determining medicinal substances in biological fluids - urine, saliva, blood, plasma or serum, cerebrospinal fluid, as well as in tissues of internal organs. Proof of concept for personalized treatment based on pharmacokinetic or metabolic properties of a drug or its metabolites. Fundamentals of pharmacogenetics, biochemical control of human susceptibility genes to a specific disease. Describe personalized medicine as a scientifically based method for finding the right medication for a particular patient. Calculation of individual dosage regimens for medicinal products based on their quantitative determination in vital fluids.

		International requirements for assessing the bioequivalence of generic drugs in vivo and in vitro. Anticipating the efficacy of pharmaceuticals at an early stage in the development of an original drug "in silico"

4.2. Sections of discipline and types of classes

№ п/п	The name of the discipline section	Lectures.	Practical classe	Lab. classes	Seminar	Independent work	Total hours
1.	Biopharmaceutical analysis (introduction)	10	10	-	-	16	36
2.	Questions of biopharmaceutical analysis	30	30	-	-	30	90
Total:		40	40			46	
Total hours - 126							

5. Лабораторный практикум

№ п/п	Name of the section of the discipline (module)	Name of the section of the discipline (module) Name of laboratory (practical) work	Total hours
1.	Biopharmaceutical analysis (introduction)	prevention of accidents, work with normative documentation, textbooks, workshops, tutorials, reference books. The order of registration of works Establishing the range of the minimum therapeutic and toxic levels of drugs in the body. Revealing the dependence of pharmacokinetic parameters and drug concentration on the state of the human body	10
2.	Questions of biopharmaceutical analysis	Features of the extraction of medicinal substances from biomaterial. Features of concentration of medicinal substances extracted from biomaterial to achieve the required limits of their detection and quantitative determination. Methods for determining medicinal substances in biological fluids - urine, saliva, blood, plasma or blood serum, cerebrospinal fluid, as well as in the tissues of internal organs. Calculation of individual dosage regimens for medicinal products based on their quantitative determination in biofluids. International requirements for the assessment of bioequivalence of generic drugs in vivo and in vitro. Application of the dissolution test for various dosage forms. The use of a dissolution tester "flow cell" in Anticipating the effectiveness of drugs. Interpretation of the results of a dissolution test	30

		performed on various instruments. Anticipating the effectiveness of pharmaceutical substances at an early stage of development of an original drug "in silico"	
Total hours:			40

MATERIAL AND TECHNICAL SUPPORT OF THE DISCIPLINE

During the program, the following are used: a personal computer, multimedia equipment, laboratory equipment, products and samples for testing.

Name of the specialized laboratory	Type of calss	Equipment identification
Room number 123 in the Shared Research and Educational Center	Lectures	Computer, multimedia projector, screen, board
Laboratories of the Shared Research and Educational Center	Laboratory exercises	Dissolution control system for solid dosage forms DISTEK "EVOLUTION 6100" with a collector of fractions "EVO 4300" Dissolution tester "flow cell" Sotax. Fourier transform infrared spectrometer 3100 FT-IR Excalibur Series, Atomic absorption spectrometer AA-240G, Inductively coupled plasma emission spectrometer Varian mod. ICP-720ES, Spectrophotometer UV / VID, CARY 100, Liquid chromatograph Agilent 1200, Agilent 1200 Infinity LC Liquid Chromatograph, Agilent 1260 Infinity II LC Liquid Chromatograph, Shimadzu Prominence liquid chromatograph with SPD-M20A detector, NMR spectrometer JEOL JNM-ECA 600 NM, Liquid chromatograph Agilent model 1290 Infinity LC, 50674-12, DAD, with mass-selective detector Agilent 6400 model 6430 LS / MSD Triple Quadrupole, Gas chromatograph Agilent 7890A with automatic headspace sampler sampler Agilent 7694E,

		Liquid chromatograph Pro Star Varian with spectro-photometric detector, Saturn chromato-mass spectrometer mod. 2100, pH meter-ionomer Ecotest-120, etc.

Main literature	
American Chemical Society (ACS) - electronic journals	http://pubs.acs.org/
Cambridge Journals	https://www.cambridge.org/core
Electronic resources Springer	https://rd.springer.com/
additional literature	
PROQUEST DISSERTATIONS AND THESES GLOBAL	http://search.proquest.com/
Reaxys, Reaxys Medicinal Chemistry	https://www.reaxys.com/

Intermediate Certificate Assessment Fund

Passport of the fund of assessment tools for the discipline biotechnology 2020/2021 H

Direction / Specialty 06/33/01 "Pharmacy" postgraduate study in the direction of Pharmaceutical technology (in collaboration with the University of Basel) Discipline «Research and Anticipating the effectiveness of drugs (in vivo, in vitro, in silico) / Изучение и прогнозирование эффективности лекарственных препаратов (in vivo, in vitro, in silico)»

Controlled competence code	Controlled discipline topic	forms of control of the level of mastering OOP			Scores
		Classroom work		Independent work	
		Work in class	Attending lectures	abstract	
OPC-3, OPC-4, OPC-5, PC-1, PC-2	Biopharmaceutical analysis (introduction)	20	5	10	35
OPC-3, OPC-4, OPC-5, PC-1, PC-2	Questions of biopharmaceutical analysis	40	5	20	65
		60	10	30	100

Questions to the post-graduate certification in the discipline «Research and Anticipating the effectiveness of drugs (in vivo, in vitro, in silico) / Изучение и прогнозирование эффективности лекарственных препаратов (in vivo, in vitro, in silico)»

1. The connection of problems of pharmaceutical chemistry with pharmacokinetics and pharmacodynamics.
2. The effectiveness of the drug's impact depends on the ways of its introduction into the body.
3. Pharmacokinetic parameters.
4. Fundamentals of pharmacodynamics.
5. The concept of biopharmaceutical factors.
6. Methods for establishing the bioavailability of medicinal products.
7. Features of the extraction of medicinal substances from biomaterial.
8. Concentration characteristics of medicinal substances extracted from bio-material in order to achieve the required limits of their detection and quantitative determination.
9. Methods for determining medicinal substances in biological fluids - urine, saliva, blood, plasma or blood serum, cerebrospinal fluid, as well as in the tissues of internal organs.
10. Calculation of individual dosage regimens for medicinal products based on their quantitative determination in biofluids.
11. International requirements for the assessment of bioequivalence of generic drugs in vivo and in vitro.
12. Application of the dissolution test for various dosage forms.
13. Use of the "flow cell" dissolution tester in predicting the effectiveness of drugs.
14. Interpretation of the results of the dissolution test carried out on various instruments
15. Anticipating the effectiveness of pharmaceutical substances at an early stage of development of an original drug "in silico".

The developer

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