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**Federal State Autonomous Educational Institution of Higher Education  
PEOPLES' FRIENDSHIP UNIVERSITY OF RUSSIA  
NAMED AFTER PATRICE LUMUMBA  
RUDN University**

**Institute of Medicine**

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educational division (faculty/institute/academy) as higher education programme developer

**COURSE SYLLABUS**

**CLINICAL PHARMACOLOGY**

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course title

**Recommended by the Didactic Council for the Education Field of:**

**31.05.01 General Medicine**

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field of studies / speciality code and title

**The course instruction is implemented within the professional education programme of higher education:**

**General Medicine**

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higher education programme profile/specialisation title

## 1. COURSE GOALS

«General Medicine» of the field 31.05.01 «General Medicine» and is studied in the 11<sup>th</sup> semester of the 6<sup>th</sup> year. The discipline is provided by the Department of Pharmacology and Clinical Pharmacology. The discipline consists of 2 modules and 12 topics and is targeted at the study of general and specific issues of clinical pharmacology for mastering the skills of rational prescribing and control of its efficacy and safety.

The aim of the course «**Clinical pharmacology**» is to equip students with theoretical knowledge and practical skills of choosing and prescribing effective, safe and economically reasonable drugs in order to be able to use rational and personalized pharmacotherapy based on the authentic data on pharmacokinetics, pharmacodynamics, drug interactions, adverse drug reactions, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology and principles of evidence-based medicine.

## 2. REQUIREMENTS FOR LEARNING OUTCOMES

The mastering of the course «**Clinical pharmacology**» is aimed at the formation of the following competencies of students: GC-1, GPC-3, GPC-7, GPC-9, PC-3

*Table 2.1. List of competences that students acquire through the course study*

<b>Competence code</b>	<b>Competence</b>	<b>Indicators of Competence Formation</b> (within the framework of this discipline)
GC-1	Being able to implement critical analysis of problem situations based on systems approach, develop an action strategy.	GC-1.2. Assessing in a critical way the reliability of information sources, working with contradictory information from different sources. GC-1.3. Understanding the trends, strategic goals, problems in the field of healthcare/ being aware of regulatory framework to develop a strategy.
GPC-3	Being able to counter doping in sports and fight against it.	GPC-3.2. Being able to analyse biochemical, physical and chemical, and molecular and biological mechanisms of the development of pathological processes in the cells of the athlete's body tissues when taking prohibited drugs; defining the principles of the biochemical processes when taking illegal drugs.
GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	GPC-7.1. Mastering skills in the methods of general clinical examination, interpretation of laboratory results, instrumental diagnostic methods. GPC-7.3. Being able to choose medicinal drugs for diagnostics, treatment and prevention of diseases, to assess their efficacy, safety and drug interactions;

GPC-9	Being able to implement the principles of quality management in professional activity.	GPC-9.2. Being able to analyse and critically assess the professional activity quality according to the target values.
PC-3	Being able to prescribe treatment and monitor its efficacy and safety.	PC-3.1. Being able to develop a treatment plan for a disease or condition taking into account the diagnosis, age and clinical picture in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the standards of medical care. PC-3.2. Being able to prescribe medicinal drugs, medical devices and medical nutrition taking into account the diagnosis, age and clinical picture of the disease and in accordance with the current procedures for the provision of medical care, clinical guidelines (treatment protocols) on the provision of medical care taking into account the standards of medical care. PC-3.4. Being able to assess the efficacy and safety of the use of drugs, medical devices, medical nutrition and other treatment methods.

### 3. THE COURSE IN HIGHER EDUCATION PROGRAMME STRUCTURE

*The course refers to the core/variable/elective\* component of (B1) block of the higher educational programme curriculum.*

\* - Underline whatever applicable.

Within the higher education programme students also master other (modules) and / or internships that contribute to the achievement of the expected learning outcomes as results of the course study.

*Table 3.1. The list of the higher education programme components/disciplines that contribute to the achievement of the expected learning outcomes as the course study results*

Competence code	Competence descriptor	Previous courses/modules*	Subsequent courses/modules*
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GC-1	Being able to implement critical analysis of problem situations based on systems approach, develop an action strategy.	Philosophy; Hygiene; Public health and healthcare, health economics; Epidemiology; Mathematics; Propaedeutics of internal diseases; Chemistry; Medical informatics; Evidence-based medicine; Bioorganic chemistry; Physics; History of medicine; Socially significant projects in medicine; <i>Economics</i> **	
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GPC-3	Being able to counter doping in sports and fight against it.	Medical recovery; Chemistry; Bioorganic chemistry; Pharmacology; Physical culture; Applied physical education	
GPC-7	Being able to prescribe treatment and monitor its efficacy and safety.	General medical practice: assistant of physician in out-patient primary care; General surgery; Otorhinolaryngology; Polyclinical therapy; Ophthalmology; Cardiology in quests; Histology, embryology, cytology; Normal physiology; Propaedeutics of internal diseases; Pediatrics; Pharmacology	Polyclinical therapy; Maxillofacial surgery
GPC-9	Being able to implement the principles of quality management in professional activity.	Organization of special patient care; Introduction to speciality; Public health and healthcare, health economics; Practice on obtaining primary professional skills: assistant of junior medical staff	
PC-3	Being able to prescribe treatment and monitor its efficacy and safety.	Surgery practice: assistant of the surgeon; Therapy practice: assistant of the therapist; General medical practice: assistant of the physician in out-patient primary care; Obstetrics and gynecology practice: assistant of the obstetrician; Obstetrics and gynecology practice: assistant of the gynecologist; General medical practice: assistant of the pediatrician; Dermatovenerology; Neurology, medical genetics, neurosurgery; Faculty surgery; Professional diseases; Hospital therapy; Polyclinical therapy; Hospital surgery, paediatric surgery; Pediatrics; <i>Topical Issues of Neonatology</i> **; Obstetrics and gynecology; Otorhinolaryngology; Traumatology, orthopedy; Cardiology in quests; <i>Clinical trials</i> **; Faculty therapy; Ophthalmology; Urology; Infectious diseases; Psychiatry, medical psychology; <i>Fundamentals of integrative medicine</i> **; <i>Fundamentals of nutrition in childhood</i> **; Fundamentals of therapeutic nutrition; <i>Introduction to nutrition</i> **; Experimental oncology; Pharmacology; Geriatrics and palliative medicine	Hospital therapy; Endocrinology; Polyclinical therapy; Hospital surgery, paediatric surgery; <i>Out-patient cardiology</i> **; Maxillofacial surgery; Allergology; Phthisiology; Endoscopic urology; Telemedicine; Out-patient pulmonology; Reproductive health

\* To be filled in according to the competence matrix of the higher education programme.

#### 4. COURSE WORKLOAD AND ACADEMIC ACTIVITIES

The total workload of the course is 3 credits (108 academic hours).

Table 4.1. Types of academic activities during the periods of higher education programme mastering (**full-time training**)\*

Type of academic activities	Total academic	Semesters/training modules
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		<b>hours</b>	<b>11</b>
<i>Contact academic hours</i>		<b>51</b>	<b>51</b>
Lectures (LC)		0	0
Lab work (LW)		51	51
Seminars (workshops/tutorials) (S)		0	0
<i>Self-studies</i>		39	39
<i>Evaluation and assessment (exam/passing/failing grade)</i>		18	18
<b>Total workload of the discipline</b>	ac.h.	<b>108</b>	<b>108</b>
	credits	<b>3</b>	<b>3</b>

## 5. THE COURSE MODULES AND CONTENTS

Table 5.1. The content of the discipline and types of academic activities

Course module title	Course module contents (topics)	Academic activities types
Module 1 General issues of clinical pharmacology.	1.1 Subject and tasks of clinical pharmacology. Clinical research. Principles of evidence-based medicine. Fundamentals of clinical pharmacodynamics. Clinical pharmacology as a basis for rational drug selection, individualization, and safe use of medicinal products; aims, objectives and methods of the discipline, clinical trial design, assessment of the quality of evidence, and application of the principles of evidence-based medicine in real clinical practice. Mechanisms of action of medicinal products, receptor-mediated and non-receptor effects, dose-response relationship, therapeutic range, clinically meaningful endpoints, and factors determining the variability of the pharmacodynamic response in different categories of patients.	LW
	1.2 Fundamentals of clinical pharmacokinetics. Drug dosing. The main pharmacokinetic processes and parameters, principles for selecting dosing regimens, therapeutic drug monitoring, as well as specific approaches to dose adjustment in renal and hepatic insufficiency, in children, elderly patients, and patients with comorbidities.	LW
	1.3 Drug-drug interactions. Drug safety. Pharmacovigilance. Doping in sport. Pharmacokinetic and pharmacodynamic drug interactions, clinically significant drug combinations, the role of metabolic enzymes and transport systems, as well as the fundamentals of pharmacogenetics and the personalization of pharmacotherapy. Classification, risk factors, methods for detecting adverse drug reactions, assessing causality, preventing and managing them, as well as the basics of pharmacovigilance and improving the safety of pharmacotherapy. Definition of doping and the main classes of prohibited substances, medical consequences of their use, and the ethical and legal aspects of physician involvement in anti-doping activities.	LW
	1.4 Principles of efficacy and safety assessment of drugs. Fundamentals of rational Pharmacotherapy (P- drug and P-treatment). Approaches to the selection of medicinal products based on the balance of efficacy, safety, convenience of use, and pharmacoeconomic feasibility; assessment of clinical outcomes, and of the risks and benefits of therapy in various clinical situations.	LW

Module 2 Specific issues of clinical pharmacology.	2.1 Medicinal products acting on the cardiovascular system: rational choice, clinical use, prevention of cardiovascular risk. Principles of rational use of medicinal products in arterial hypertension, ischemic heart disease, chronic heart failure, and arrhythmias, considering clinical guidelines, comorbidities, and the need for long-term cardiovascular prevention.	LW
	2.2 Hypolipidemic agents and metabolic modulators: clinical efficacy, safety, Strategies of combination therapy. Pathophysiological foundations of dyslipidemia and atherosclerosis; classification and mechanisms of action of hypolipidemic drugs; target lipid levels, monitoring of efficacy and safety, as well as the role of combination therapy, especially in cases of insufficient response to statins or statin intolerance.	LW
	2.3 Medicinal products affecting hemostasis and hematopoiesis, management of Bleeding and thrombosis risk. Drugs for the correction of anemias and cytopenia. Clinical pharmacology of antiplatelet agents, anticoagulants (including direct oral anticoagulants), thrombolytics and drugs affecting hematopoiesis; selection of therapy based on the balance between thrombosis and bleeding risk, specific features of monitoring, and contemporary approaches to the prevention of complications.	LW
	2.4 Medicinal products acting on the respiratory system: pharmacotherapy of asthma, COPD and acute respiratory conditions, inhalation technologies. Principles of pharmacotherapy for bronchial asthma, COPD, and other respiratory diseases; selection of bronchodilators, inhaled glucocorticoids, and combination regimens, as well as the role of biological agents in severe bronchial asthma and phenotype-oriented treatment.	LW
	2.5 Medicinal products acting on the digestive system: therapy of acid-related diseases, intestinal, liver, pancreatic disorders. Rational use of drugs in acid-related diseases, motility disorders, inflammatory bowel diseases, liver and biliary tract pathology; selection of therapy considering efficacy, safety, and drug-drug interactions.	LW
	2.6 Medicinal products used in endocrinology: glucose-lowering and hormone therapy, monitoring of efficacy and safety. Clinical pharmacology of insulins, oral and injectable glucose-lowering agents, as well as drugs for the treatment of thyroid, adrenal diseases and osteoporosis; personalization of therapy considering the cardiorenal benefits of modern agents.	LW
	2.7 Medicinal products used in immune disorders and allergic conditions: immunomodulators, antihistamines, biological therapy. General characteristics of vaccines, immunoglobulins, sera, monoclonal antibodies and other immunobiological products, their clinical use, issues of immunogenicity, interchangeability, biosimilars, and safety monitoring in current practice.	LW
	2.8 Use of anti-infective agents in accordance with the principles of rational antimicrobial therapy. Classification, mechanisms of action, and principles of rational use of antibacterial, antiviral, antifungal, and antiparasitic agents; selection of therapy considering the site of infection, pathogen resistance, pharmacokinetic-pharmacodynamic parameters, and the principles of antimicrobial stewardship.	LW

\* - to be filled in only for full-time training: *LC* - lectures; *LW* - lab work; *S* - seminars

## 6. CLASSROOM EQUIPMENT AND TECHNOLOGY SUPPORT REQUIREMENT

Table 6.1. Classroom equipment and technology support requirements

Type of academic activities	Classroom equipment	Specialised educational / laboratory equipment, software, and materials for course study (if necessary)
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Computer lab	Computer classroom for classes, individual and group consultations, ongoing control and interim attestation equipped with PCs (26), whiteboard (screen) and technical means for multimedia presentations.	Electronic educational environment TUIS RUDN, Software (MS products).
Lab-work	Classroom for lab work, individual and group consultations, ongoing control and interim attestation equipped with laboratory and diagnostic equipment of clinical bases of the department.	Electronic educational environment TUIS RUDN, Software (MS products), multimedia projector, interactive board, demo lab and medical equipment samples.
Seminar	Classroom for practical classes, individual and group consultations, ongoing control and interim attestation equipped with a set of specialized furniture and technical means for multimedia presentations.	Electronic educational environment TUIS RUDN, Software (MS products), multimedia projector, interactive board, demo medical equipment samples.
<i>Self-studies</i>	Classroom for self-study (might be used for lab work and consultations) equipped with a set of specialized furniture and PCs with access to electronic educational environment.	Electronic educational environment TUIS RUDN, Software (MS products).

\* - classroom for self-studies **MUST** be specified!

## 7. RESOURCES RECOMMENDED FOR COURSE STUDY

### a) Main readings:

1. Basic and Clinical Pharmacology / B. Katzung, S. Masters. - 16th ed.; Книга на английском языке. - New York: McGraw-Hill, 2024. - 1368 p.: il. - (Lange Medical Books). - ISBN 978-1260463309.

### b) Additional reading:

1. S.B. Fitilev, I.I. Shkrebneva, A.V. Vozzhaev. The Fundamentals of Rational Pharmacotherapy (Problem-Based Method of Teaching Clinical Pharmacology or How to Create Your Own Guideline) (учебное пособие на английском языке). Москва: РУДН, 2017. – 85 с.

### *Internet (based) sources*

1. Electronic Library System (ELS) of the RUDN University and third-party ELS, to which university students have access on the basis of concluded contracts:

- Electronic Library System (ELS) of the RUDN <http://lib.rudn.ru/MegaPro/Web>
- ELS «Университетская библиотека онлайн» <http://www.biblioclub.ru>
- ELS Юрайт <http://www.biblio-online.ru>
- ELS «Консультант студента» [www.studentlibrary.ru](http://www.studentlibrary.ru)
- ScienceDirect <https://www.sciencedirect.com/>
- Springer <https://www.springer.com/gp>

2. Databases and search engines:

- State register of drugs <http://www.drugreg.ru/Bases/WebReestrQuery.asp>
- Source on pharmacogenetics <http://www.pharmgkb.org/>
- Source of drug interactions <http://medicine.iupui.edu/flockhart/>

*Learning toolkits for self-studies during the development of the discipline\*:*

1. Course of lectures for the discipline «Clinical pharmacology».

\* - All teaching materials for self-studying of students are placed in accordance with the current procedure on the discipline page in the Electronic educational environment TUIS RUDN.

**DEVELOPERS:**

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