

**MINISTRY OF SCIENCE AND HIGHER EDUCATION
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**FEDERAL STATE AUTONOMOUS EDUCATIONAL INSTITUTION OF
HIGHER EDUCATION
NORTH-CAUCASUS FEDERAL UNIVERSITY**

Methodological Guidelines
for Students on arranging and performing independent work
in the Discipline of Clinical Pharmacology
for Students majoring (Specialty) in 31.05.01 General Medicine

Methodological Recommendations for Studying Theoretical Material

When performing the independent study of theoretical material, the student must follow the rules as set below. The working curriculum of the respective academic discipline shall be recommended to be used as the basis for such activity. According to the schedule of classroom lessons and independent work, a different number of hours is to be allocated for studying individual topics. A significant portion of the student's independent work should be allocated to mastering the material on the covered topic, writing a summary (notes) on the specified theoretical blocks, and searching for additional literature based on the NCFU library and via the Internet system. The lecture material shall not cover all theoretical material; the greater part of it must be mastered through independent work. Given the above, working with the recommended literature is mandatory. Special attention must be paid to the content of the main provisions and conclusions, the explanation of phenomena and facts, and the understanding of the practical application of the theoretical issues under consideration. In the process of this work, the student should strive to understand and memorize the main provisions of the material being considered, the examples illustrating it, as well as to understand the illustrative material. Preparation should be completed by drawing up a plan (summary/notes) on the material (issue) being studied. This allows for the creation of a concentrated, concise representation of the issues being studied. First, studying the recommended literature is to be done. Special attention must be paid to the content of the main provisions and conclusions, the explanation of phenomena and facts, and the understanding of the practical application of the theoretical issues under consideration.

During this work, the student should strive to understand and memorize the main provisions of the material being considered, the examples illustrating it, as well as to understand the illustrative material. Preparation should be completed by drawing up a plan (summary/notes) on the material (issue) being studied. This allows for the creation of a concentrated, concise representation of the issues being studied. If necessary, one should seek (advice) consultation from the instructor. When going to a consultation, it is necessary to thoroughly think through the questions that require clarification. Keeping records contributes to turning reading into an active process, mobilizing motor memory along with visual memory. The following should be born in mind: a student who systematically keeps records creates their own individual stock of auxiliary materials for a quick review of what has been read and for the mobilization of accumulated knowledge. Records are especially important and useful when they reflect the thoughts that arose during independent work.

It is important to develop the students' capacity to compare sources and to think through the material being studied.

Improving note-taking skills among students is of great importance.

The instructor may recommend the following main forms of recording to students: a plan (simple and detailed), excerpts, and theses (abstracts).

The results of note-taking can be presented in various forms.

- A plan is an outline of the read material, a brief (or detailed) list of questions reflecting the structure and sequence of the material.
- A detailed plan fully replaces a summary.
- A summary (notes) is a systematized, logical presentation of the source material. Four types of summaries are distinguished:
 - Outline-summary (Plan-notes) – this is an expanded, detailed plan in which sufficiently detailed records are provided for those points of the plan that need explanation.
 - Textual summary – this is the reproduction of the most important provisions and facts of the source.
 - Free summary – these are clearly and briefly formulated (stated) main provisions resulting from a deep understanding of the material. It may contain excerpts, quotations, and theses; part of the material may be represented by a plan.

- Theme-based summary – this is compiled on the basis of studying a number of sources and gives a more or less exhaustive answer according to a certain scheme (issue).

Methodological Guidelines for the Preparation for Practical Activities

When preparing for practical activities, the recommendation implies studying the control questions for the given lesson and the theoretical material from one's own notes.

The main form of work during the lessons is an interview (discussion). Each student must be ready to speak on all issues raised in the plan and demonstrate maximum activity during their consideration.

The speech must be constructed freely, convincingly, and with arguments. The instructor ensures that the speech is not reduced to a reproductive level (simple reproduction of the text); simple reading of the summary is also not allowed.

It is necessary for the speaker to show their own attitude towards what they are talking about, express their personal opinion and understanding, substantiate it, and be able to draw the correct conclusions from what has been said. In doing so, the student may refer to the entries in the summary, directly to the primary sources, use knowledge of previously studied disciplines, etc. In addition, to obtain a grade at an advanced level, students solve situational tasks based on the results of the mastered topics.

During the execution of practical works, a defense of practical skills is provided, the full list of which is specified in the fund of assessment tools.

Methodological Recommendations for the Preparation of Presentations and Reports

The report must contain elements of novelty; along with the fundamental aspect, an analysis of the current state of the problem under study must be carried out, as well as inclusion in regional issues. The report must include an introduction, a theoretical part, a conclusion, a list of literature, and a presentation that reveals the essence of the topic in graphs, pictures, diagrams, and formulas.

The report is recommended to be submitted on 1 printed sheet. The text of the work must be printed with 1.5 line spacing on one side of a standard sheet (A4) of white paper.

The text and other printed elements of the work must be black, and the contours of letters and signs must be clear, without halos and shading. The font must be Times New Roman, size 14. The titles of chapters and paragraphs are highlighted in bold. The sheet with text must have margins: left – 30 mm, right – 10 mm, top – 20 mm, bottom – 20 mm.

Page numbering of the text is done in the lower right corner of the sheet. It is necessary to number pages starting from the page where the Introduction is printed, on which the number 3 is placed. After that, all pages, including appendices, are numbered.

A space equal to two intervals is placed between the title of the chapter and the title of the paragraph of this chapter, and the title of the paragraph must not be separated from the text of this paragraph by a space. The titles of paragraphs shall be separated from the text of the previous paragraph by a space equal to two intervals. Each chapter, as well as the introduction, conclusions, appendices, and the list of used literature, begin on a new page. The word Chapter is not to be written. Chapters have ordinal numbers within the entire work, designated by Arabic numerals (for example: 1, 2, 3), followed by a period.

The word **PARAGRAPH** or the paragraph symbol (§) is not placed in the title. Paragraphs have ordinal numbers within the chapters, designated by Arabic numerals (for example: 1.1. and 1.2.).

Headings of chapters and paragraphs in the text must be centered; a period shall not be placed at the end of the title of the chapter and paragraph. It is not allowed to hyphenate (transfer) a part of a word in a heading. 4.5. The numbering of tables and figures can be running (continuous) or relate to the number of the chapter and paragraph. For example, if a table or a figure is included in the text of the first paragraph of the second chapter, the numbering is as follows: Table 2.1.1., Fig. 2.1.1.

The last digit means the ordinal number of the table (or figure) in this paragraph.
The table is to be placed as the next page after the first mention of it in the text.

Aim and Objectives of Mastering the Discipline (Module)

- Aim of mastering the discipline is to help students develop the skills to choose effective and safe medications and their dosing regimens based on clinical guidelines, diagnostic and treatment standards, formularies, and the list of essential and important medications for modern individualized and controlled pharmacotherapy, using basic data on pharmacokinetics, pharmacodynamics, pharmacogenetics, pharmacoeconomics, pharmacoepidemiology, drug interactions, and adverse drug reactions, as well as the principles of evidence-based medicine

- Objectives of mastering the discipline Clinical Pharmacology:

formation of skills to identify individual differences in the effect of drugs depending on the patient's condition and the details of the disease pathogenesis;

formation of clinical and pharmacological thinking in the choice of the volume of pharmacotherapy;

training specialists who can work in their respective fields according to modern clinical and pharmacological standards, combining them with the individuality of each clinical situation, taking into account the latest achievements in medical science;

developing a systematic approach to analyzing medical information based on the comprehensive principles of evidence-based medicine;

developing students' ability to provide effective, safe, and personalized pharmacotherapy based on their knowledge of the rational use of medications.

Theme 1

Evidence-Based Medicine in Clinical Pharmacology

Aim

To develop students' ability to apply the principles of evidence-based medicine to clinical pharmacology, critically evaluate clinical research, assess the benefit–risk profile of medicinal products, and make rational, safe and individualized pharmacotherapeutic decisions based on reliable evidence, clinical guidelines and patient characteristics.

Control Questions

1. Define evidence-based medicine and explain its principal components.
2. What is the role of clinical pharmacology in evidence-based healthcare?

3. Distinguish between clinical efficacy, clinical effectiveness and safety.
4. What is the hierarchy of scientific evidence?
5. Compare randomized controlled trials, cohort studies and case-control studies.
6. What is randomization and why is it important in clinical trials?
7. Explain the purpose of blinding and identify the main types of blinding.
8. What is a systematic review and how does it differ from a narrative review?
9. Define meta-analysis and explain the meaning of heterogeneity between studies.
10. What is a confidence interval and how should it be interpreted?
11. Distinguish relative risk, odds ratio, absolute risk reduction and number needed to treat.
12. What is a clinically important outcome and how does it differ from a surrogate endpoint?
13. Explain the concepts of internal and external validity.
14. What is publication bias and how can it affect clinical recommendations?
15. What are the main stages of a clinical trial involving a medicinal product?
16. Explain the importance of pharmacovigilance and post-marketing surveillance.
17. What is the benefit-risk assessment of a medicinal product?
18. How should clinical guidelines and formularies be used in individualized pharmacotherapy?

Theme 2

Clinical pharmacology in cardiology.

Aim

To develop the ability to select and use medicinal products rationally in cardiovascular diseases, taking into account the clinical diagnosis, disease severity, comorbidities, pharmacokinetic and pharmacodynamic characteristics, drug interactions, contraindications, adverse reactions and evidence-based treatment recommendations.

Control Questions

1. What are the principal pharmacological approaches to the treatment of arterial hypertension?
2. Explain the role of the renin-angiotensin-aldosterone system in blood-pressure regulation.
3. Compare the mechanisms of action of ACE inhibitors and angiotensin II receptor blockers.
4. Why can ACE inhibitors cause a persistent dry cough?
5. What are the main indications and contraindications for beta-adrenoceptor blockers?
6. Compare dihydropyridine and non-dihydropyridine calcium-channel blockers.
7. Describe the main adverse effects of thiazide and thiazide-like diuretics.
8. What is the pharmacological rationale for using loop diuretics in congestive heart failure?
9. Explain the mechanism of action of spironolactone and its role in heart-failure therapy.
10. Describe the mechanism of action and therapeutic monitoring of digoxin.
11. What clinical signs and symptoms may indicate digoxin toxicity?
12. How do hypokalemia and renal impairment affect the safety of digoxin therapy?
13. Classify antianginal agents according to their principal pharmacological effects.
14. Explain how organic nitrates reduce myocardial oxygen demand.
15. What is nitrate tolerance and how can it be prevented?

16. Describe the main principles of pharmacotherapy for atrial fibrillation.
17. Classify antiarrhythmic medicines according to the Vaughan–Williams system.
18. What is the role of statins in the primary and secondary prevention of cardiovascular events?
19. Which laboratory parameters should be monitored during statin therapy?
20. What factors should be considered when selecting an antithrombotic agent?

Theme 3

Clinical pharmacology in pulmonology.

Aim

To develop students' competence in the evidence-based selection, dosing and monitoring of medicines used in bronchial asthma, chronic obstructive pulmonary disease and other respiratory disorders, with particular attention to inhalation therapy, treatment adherence, adverse reactions and individual patient characteristics.

Control Questions

1. What are the principal pharmacological objectives in the treatment of bronchial asthma?
2. Distinguish between reliever medicines and controller medicines in asthma management.
3. Explain the mechanism of action of short-acting beta-2-adrenoceptor agonists.
4. Compare short-acting and long-acting beta-2-adrenoceptor agonists.
5. What is the role of inhaled glucocorticoids in the treatment of asthma?
6. Which local adverse effects may occur during inhaled corticosteroid therapy?
7. Why should patients rinse their mouth after inhalation of a corticosteroid?
8. Compare the pharmacological properties of ipratropium and tiotropium.
9. What are the main clinical indications for leukotriene receptor antagonists?
10. Describe the mechanism of action and limitations of theophylline.
11. What factors may influence the pharmacokinetics of theophylline?
12. What are the main principles of pharmacotherapy for chronic obstructive pulmonary disease?
13. Compare bronchodilator therapy in asthma and COPD.
14. What is the role of systemic glucocorticoids in acute exacerbations of respiratory disease?
15. Which factors contribute to poor adherence to inhaled treatment?
16. How should the correct use of an inhaler be assessed?
17. What are the principal adverse effects of beta-2-adrenoceptor agonists?
18. When are mucolytic or expectorant medicines clinically justified?

Theme 4

Clinical pharmacology in gastroenterology.

Aim

To develop the ability to select and monitor pharmacotherapy for common gastrointestinal diseases, including acid-related disorders, gastro-oesophageal reflux disease, peptic ulcer disease,

dyspepsia, diarrhoea, constipation and hepatobiliary disorders, while considering drug interactions, contraindications and patient-specific risks.

Control Questions

1. What are the main pharmacological mechanisms involved in gastric acid secretion?
2. Compare proton-pump inhibitors and H₂-histamine receptor antagonists.
3. What are the principal clinical indications for proton-pump inhibitors?
4. Describe the recommended principles of safe long-term proton-pump inhibitor therapy.
5. What is the mechanism of action of antacid medicines?
6. What are the limitations and possible adverse effects of antacid therapy?
7. Explain the role of mucosal protective agents in peptic ulcer disease.
8. What are the pharmacological principles of *Helicobacter pylori* eradication therapy?
9. Why is combination therapy used for *H. pylori* infection?
10. What are the main pharmacological approaches to gastro-oesophageal reflux disease?
11. Compare the mechanisms of action of metoclopramide and domperidone.
12. What are the main indications and contraindications for prokinetic medicines?
13. Classify laxatives according to their mechanism of action.
14. What are the principal risks associated with prolonged use of stimulant laxatives?
15. Explain the mechanism of action and clinical use of loperamide.
16. When should antimicrobials not be used in the treatment of acute diarrhoea?
17. What is the pharmacological role of lactulose in hepatic encephalopathy?
18. What are the main principles of rational hepatoprotective therapy?
19. Which drug interactions are clinically important in gastrointestinal pharmacotherapy?
20. What factors should be considered when prescribing medicines to patients with hepatic impairment?

Theme 5

Clinical pharmacology in endocrinology.

Aim

To develop students' ability to select, prescribe and monitor medicines used in endocrine disorders, particularly diabetes mellitus, thyroid diseases, osteoporosis and adrenal disorders, using evidence-based principles and taking into account efficacy, safety, comorbidities, age, renal function and the risk of endocrine emergencies.

Control Questions

1. What are the main pharmacological goals in the treatment of diabetes mellitus?
2. Classify insulin preparations according to their duration of action.
3. Explain the mechanism of action of insulin at the cellular level.
4. What are the principal indications for insulin therapy?
5. Define hypoglycemia and describe its main clinical manifestations.
6. How should severe hypoglycemia be treated?
7. Explain the mechanism of action of metformin.
8. Why does metformin usually not cause hypoglycemia when used as monotherapy?

9. What is lactic acidosis and why is it a clinically important risk of metformin therapy?
10. Describe the mechanism of action and adverse effects of sulfonylureas.
11. Compare GLP-1 receptor agonists and DPP-4 inhibitors.
12. Explain the mechanism of action and clinical benefits of SGLT2 inhibitors.
13. What renal and cardiovascular factors should be considered before prescribing SGLT2 inhibitors?
14. Describe the biosynthesis and physiological effects of thyroid hormones.
15. What are the principal indications for levothyroxine therapy?
16. Classify antithyroid medicines and describe the mechanism of thioamides.
17. What serious adverse reactions may occur during thiamazole therapy?
18. Explain the role of glucocorticoids in adrenal insufficiency.
19. Why must prolonged glucocorticoid therapy not be discontinued abruptly?
20. What are the main pharmacological strategies for preventing and treating osteoporosis?

Theme 6

Clinical pharmacology in allergology and immunology.

Aim

To develop students' ability to recognize common allergic and immune-mediated disorders and to select safe, effective and evidence-based pharmacotherapy, including antihistamines, glucocorticoids, immunomodulators and emergency treatment for severe hypersensitivity reactions.

Control Questions

1. Define hypersensitivity and distinguish the principal types of allergic reactions.
2. Explain the immunological mechanism of an immediate IgE-mediated allergic reaction.
3. What is the role of histamine in the development of allergic symptoms?
4. Classify H1-histamine receptor antagonists into first- and second-generation agents.
5. Compare the sedative and anticholinergic effects of first- and second-generation antihistamines.
6. What are the principal clinical indications for antihistamine medicines?
7. Explain the mechanism of action of intranasal and inhaled glucocorticoids in allergic diseases.
8. What are the main adverse effects of prolonged systemic glucocorticoid therapy?
9. Describe the first-line treatment of anaphylaxis.
10. What is the recommended route of administration for adrenaline in anaphylaxis?
11. Which medicines may be used as adjunctive therapy in anaphylaxis?
12. Why must antihistamines and glucocorticoids not replace adrenaline in anaphylaxis?
13. What is allergic rhinitis and how is it treated pharmacologically?
14. Compare the pharmacological treatment of mild and severe allergic asthma.
15. What are immunosuppressants and when are they clinically indicated?
16. Explain the mechanism of action of calcineurin inhibitors.
17. What are the principal adverse effects of cyclosporine and tacrolimus?
18. Why should patients receiving biologic immunomodulators be screened for latent infections?
19. Distinguish between active and passive immunization.
20. What is the role of pharmacovigilance in the monitoring of immunomodulatory therapy?

List of Main and Additional Literature Required for Mastering the Discipline (Module)

List of Main Literature:

1. Kukes, V. G. Clinical Pharmacology and Pharmacotherapy: Textbook / edited by V. G. Kukes, A. K. Starodubtsev, and E. V. Shikh. - 4th edition, revised and expanded. and add. - Moscow: GEOTAR-Media, 2021. - 880 p. - ISBN 978-5-9704-6435-9. - Text: electronic // Electronic Library System "Student Consultant": [website]. - URL: <https://www.studentlibrary.ru/book/ISBN9785970464359>

List of Additional Literature:

1. Clinical pharmacology, pharmacological therapy : educational and methodological manual / M. R. Konorev, O. P. Dorozhkin, O. V. Kurlyuk [et al.]. — 2nd ed., revised. and add. — Vitebsk : VSMU, 2022. — 400 p. — ISBN 978-985-580-112-3. — Text : electronic // Lan : electronic library system. — URL: <https://e.lanbook.com/book/302624>
2. Clinical pharmacology. Pharmacotherapy : textbook / A. V. Matveenko, T. A. Zamoshchina, O. E. Vaizova [et al.]. — Tomsk : SibGMU, 2013. — 196 p. — Text : electronic // Lan : electronic library system. — URL: <https://e.lanbook.com/book/105899>
3. Petrov, V. I. Clinical Pharmacology and Pharmacotherapy in Real Medical Practice : Master Class : Textbook / V. I. Petrov. - Moscow : GEOTAR-Media, 2015. - 880 p. - ISBN 978-5-9704-3505-2. - Text : electronic // Electronic Library System "Student's Consultant" : [website]. - URL : <https://www.studentlibrary.ru/book/ISBN9785970435052>
4. A guide to practical exercises in pharmacology : a textbook / V. A. Serebryakova, O. E. Vaizova, A.V. Matveenko [et al.]. — 3rd ed., supplement. Tomsk : SibSMU, 2018. 311 p. — Text : electronic // Lan : electronic library system. — URL: <https://e.lanbook.com/book/113563>
5. A collection of test questions on the basic course of pharmacology for students of medical specialties of all faculties : a textbook / A. Yu. Zharikov, V. M. Bryukhanov, Ya. F. Zverev [et al.]. — Barnaul : AGMU, 2018. — 338 p. — Text : electronic // Lan : electronic library system. — URL: <https://e.lanbook.com/book/158270>
6. Test assignments on the course of clinical pharmacology : educational and methodological manual : in 2 parts / I. B. Mikhailov, I. M. Kosenko, E. B. Pavlova [et al.]. — Saint Petersburg : SPbGPMU, 2020 — Part 1 — 2020. — 40 p. — ISBN 978-5-907321-48-9. — Text : electronic // Lan : electronic library system. — URL: <https://e.lanbook.com/book/174527>

List of Educational and Methodological Support for the Independent Work of Students in the Discipline (Module)

Bicheva, G.V. Guidelines for the discipline "Clinical Pharmacology" for students of the specialty 31.05.03 Dentistry [Electronic version], Stavropol: NCFU (electronic version)

List of Resources of the Information and Telecommunications Network **Internet** Required for Mastering the Discipline (Module)

1. <http://rudocor.net/> – Medical portal
2. <http://www.e-reading.club/> – Large online library
3. <http://www.pubmed.com/> – database of biomedical full-text articles
4. <http://www.spravocnikpolekarstvam.ru/> – free online pharmacological reference
5. <https://dic.academic.ru/> – dictionaries and encyclopaedias
6. <https://www.rmj.ru/> – Russian Medical Journal
7. <https://www.studentlibrary.ru/> – Student Library e-resources