**MINISTRY OF HEALTH OF THE REPUBLIC OF BELARUS**
EDUCATIONAL INSTITUTION
BELARUSIAN STATE MEDICAL UNIVERSITY



**APPROVED**
by First Vice-Rector, Professor
_____ S.V. Gubkin
_____
Reg. # УД-1.550 а/1617 /уч.

# CLINICAL PHARMACOLOGY

**Curriculum of higher educational institution in the educational discipline for the specialty:**

**1-79 01 07 «Dentistry»**

Minsk BSMU 2017

Curriculum is based on the standard educational program "Clinical Pharmacology", approved on 31 of august 2016 registration № ТД-L.550/tip

**COMPILER:**

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**RECOMMENDED FOR APPROVAL:**

by the Clinical Pharmacology Department of the Educational Institution "Belarusian State Medical University"
(protocol # 6 of 12.01.2017);

by the Methodological Commission of Dentistry of the Educational Institution "Belarusian State Medical University"
(protocol # 5 of 14.02.2017)

## EXPLANATORY NOTE

«Clinical Pharmacology» is the educational discipline containing systematized scientific knowledge and techniques in the field of Clinical Pharmacology, studying the using of drugs in human.

The aim of teaching and learning the discipline Clinical Pharmacology is to increase the efficiency and safety of use of drugs. Clinical Pharmacology is one of the most dynamically developing sciences. Every year a great number of new drugs come into clinical practice, often having no analogues among previously used. In this regard, clinical pharmacology learning should help to form the holistic view to this part of medical science, to teach a strategy of treatment choice according to individual manifestations of the disease and total clinical data comprehensive analysis.

The curriculum of the discipline "Clinical pharmacology" includes the latest scientific data on clinical pharmacology. The main aim of the curriculum is to form social, personal and professional competence.

The purpose of teaching and learning "Clinical Pharmacology" consists in forming in students the strategy of differentiated pharmacotherapy of diseases encountered in dentistry practice using the basic knowledge of clinical pharmacodynamic and pharmacokinetic interactions and possible side effects of drugs.

The tasks of studying the discipline are to develop the students' academic competences, based on the ability to self-search educational and information resources, as well as acquire and understand the knowledge of:

- the basic concepts of clinical pharmacokinetics and pharmacodynamics of drugs;
- the drugs' interactions and side effects of drugs;
- choosing the most effective and safe drugs for an individual patient;
- selection of optimal drugs' dosage regimens;
- making clinically reasonable combinations of medicines which may be used in specific clinical situations;
- predicting, detecting in the early stages, correction and prevention of adverse effects of medicines.

The tasks of teaching the discipline include the formation of students' social, personal and professional competences, based on the knowledge and application of:

- the basics of clinical pharmacology which contribute to the formation of modern pharmacotherapy skills according to effectiveness and safety of drugs;
- clinically proved approaches of rational choice of drugs in pharmacotherapy;
- methods of monitoring the safety of pharmacotherapy.

Teaching and successful learning of the discipline "Clinical Pharmacology" is carried out on the basis of the knowledge and skills previously acquired by the students in the following disciplines:

**General Chemistry.** Basics of chemical thermodynamics. Basics of chemical kinetics. Buffer system, pH calculation.

**Medical Biology and General Genetics.** Molecular genetic and cellular levels of the organization. Genetic bases of species. Genetic pathology and its manifestations. Biosphere level of organization of life. Ecology.

**Biological Chemistry.** Proteins, lipids, carbohydrates metabolism. Biochemistry of tooth tissues. Dental deposit biochemistry. The biochemical composition of saliva. The saliva mineral and organic components value in the physiology and pathology of the oral cavity organs and tissues. Calcium and phosphorus metabolism in the teeth and in the body.

**Normal physiology.** The organism reactivity role in the occurrence of dental diseases. Causes, mechanisms and manifestations of the typical disorders of the oral cavity organs and systems. The physiological function of the tooth, dental pulp and periodont.

**Pathological physiology.** The pathophysiology of pain in dental diseases. Allergic processes in dentistry. Immunological resistance of oral tissues. Disruption of homeostasis. Functions of the oral mucosa in pathological conditions.

**Microbiology, virology, immunology.** The microbial and viral flora of the oral cavity. The microflora of dental plaque. The human immune system. Antigens. Specific and nonspecific factors of protection of the oral cavity.

**General hygiene.** The impact of the environment on the origin and course of pathological processes in organs and tissues of the oral cavity. Occupational hazards and their effects on organs and tissues of the oral cavity. Normal sanitary measurements of the environment, food and water.

**Pharmacology.** Medicines used for anesthesia in dentistry. Antibiotics. Anti-inflammatory and anti-allergic drugs. Toxic effects of drugs on the human body, tissues and organs of the oral cavity.

**Internal Medicine.** Principles of examination of the patient. Basics of diagnostics of the cardiovascular and respiratory diseases. The symptoms, diagnostics and emergency care to the patients with life-threatening conditions. Clinical manifestations of occupational hazards in the oral cavity.

**Surgical diseases.** The concept of acute surgical pathology. Wounds and wound infection.

**Otorhinolaryngology.** The relationship of oral cavity with the pathology of the ear, nose and throat. The ear, nose and throat occupational diseases in the practice of a dentist.

**Therapeutic dentistry.** Etiology, pathogenesis, clinical features, classification, diagnosis and treatment of carious diseases of hard tissues of the tooth, caries, pulpitis, apical periodontitis, gingivitis and marginal periodontitis, diseases of the oral mucosa.

**Maxillofacial surgery and dental surgery.** The methods of local anesthesia in the oral and maxillofacial region. Odontogenic inflammatory diseases, trauma, pathology of salivary glands, actinomycosis of maxillofacial area: etiology, pathogenesis, clinical features, diagnosis, treatment.

The structure of the curriculum of the discipline "Clinical pharmacology" has been presented in two sections: general clinical pharmacology and clinical pharmacology of drugs.

**As a result of studying the discipline "Clinical Pharmacology" the student should**

**know:**

– the principles of rational and safe drug therapy of dental diseases;

– clinical and pharmacological characteristics of the main drugs used in dental practice in order to select the most appropriate and safe drug for individual pharmacotherapy of patients with dental pathology.

**be able to:**

– gather the pharmacological and allergic history and ensure an adequate choice of drugs for the treatment of a particular patient;

– provide emergency medical care to patients with the drug anaphylactic shock;

– inform patients about the action of medicines, rules of administering and possible manifestations of side effects.

**master:**

– be skilled in providing emergency medical care to patients with drug anaphylactic shock.

The structure of the training curriculum "Clinical Pharmacology" consists of two sections: general clinical pharmacology and specific questions of clinical pharmacology of drugs.

**Total number** of hours for the study of the discipline is 42 academic hours. Classroom hours according to the types of studies: lectures - 12 hours, practical classes - 15 hours, student independent work (self-study) – 15 hours.

Current assessment is carried out according to the syllabus of the specialty in the form of a credit (8 semester).

Form of higher education – full-time.

# THEMATIC PLAN

| Section (topic) title | Number of class hours | |
|---|---|---|
| | lectures | practical *(laboratory or seminars)* |
| **1. General and specific questions of clinical pharmacology** | | |
| 1.1. The object and purpose of "Clinical Pharmacology", stages of development, the relationship with other academic disciplines. Basics of Evidence-Based Medicine | 2 | - |
| 1.2. Clinical trials of drugs. The original and generic medicines. State regulation and clinical trials of medicines. Bioequivalence studies | 2 | - |
| 1.3. Clinical pharmacokinetics, pharmacodynamics and their relationship. Physiological and age aspects of clinical pharmacology. Clinical pharmacogenetics. | 2 | - |
| 1.4. Drug interactions. Basic principles of rational combined pharmacotherapy. Side effects of drugs. | 2 | |
| 1.5. Basics of rational antibiotic therapy | 2 | |
| 1.6. Drugs used for the hemostasis correction. | 2 | |
| **2. Clinical pharmacology of medicines** | | |
| 2.1. Clinical pharmacology of anti-inflammatory and antiallergic drugs. Anaphylactic shock | | 5 |
| 2.2. Clinical pharmacology of antibacterial, antiviral and antifungal drugs. | | 5 |
| 2.3. Analgesic drugs. Clinical pharmacology of local anesthetics. Medicinal lesions of the mucous membranes of the mouth. Medicinal herbs used in dentistry | | 5 |
| **IN ALL:** | **12** | **15** |

# CONTENT OF THE EDUCATIONAL MATERIAL

**1. General questions of clinical pharmacology**

**1.1. The objectives and tasks of "Clinical Pharmacology", stages of development, the relationship with other academic disciplines. Basics of Evidence-Based Medicine**

Definition of clinical pharmacology. The object and purposes, the stage of development of clinical pharmacology. Relationship with other biomedical and clinical disciplines. Clinical pharmacology as a basis of rational pharmacotherapy. Basics of Evidence-Based Medicine.

**1.2. Clinical trials of drugs. The original and generic medicines. State regulation and clinical trials of medicines. Bioequivalence studies**

Nomenclature and classification of medicines. Principles of Drug development. State regulation of drugs. Pharmacological Committee, its role and tasks. Purpose, objectives and methods of clinical trials. Medical, methodological and ethical aspects of clinical trials. The Ethics Committee, its role and tasks. Types and phases of clinical trials. Classification of drugs. State registration of drugs. The original and generic medicines. Principles of bioequivalence studies of generic drugs.

**1.3. Clinical pharmacokinetics, pharmacodynamics and their relationship. Physiological and age aspects of clinical pharmacology. Clinical pharmacogenetics.**

Clinical pharmacokinetics. The characteristics of the ways of drugs administration. Distribution of drugs in the body. Metabolism of drugs. Excretion of drugs. The main pharmacokinetic parameters. Bioavailability as the main indicator of pharmacokinetics. Factors influencing on the pharmacokinetics of drugs. Pharmacokinetics of drugs for prolonged use. Clinical evaluation of pharmacodynamics basic parameters. Types of pharmacologic effects of drugs. Mechanisms of action of drugs. "Dose-effect" relationship . The relationship between pharmacokinetics and pharmacodynamics. Fundamentals of rational pharmacotherapy. Pharmacologic and allergic data collection. The dosage regimen choice. Drug interactions assessment during the treatment. Prevention of drug side effects. Informing and instructing patients. Drugs legislation. Clinical prescription. Prescribing legislation.

**1.4. Drug interactions. Basic principles of rational combined pharmacotherapy. Side effects of drugs.**

The combined use of drugs is the basic principle of modern pharmacotherapy. Drug interactions and their clinical characteristics. Drug incompatibility. Classification of drug incompatibility. Clinical manifestations of drug incompatibility. Basic principles of rational drug combinations choice. Classification of adverse drug reactions. Local undesirable effects of medicinal products for systemic use. Undesirable systemic effects of medicinal products for topical use. Basic principles of forecasting and prevention of adverse drug reactions. Treatment and rehabilitation of patients with adverse drug reactions. The principles of

informing of patients and their relatives about the possible adverse drug reactions. Identification and registration of adverse drug reactions. Adverse drug reactions reporting.

**1.5. Basics of rational antibiotic therapy**

Antimicrobial drugs classification. Peculiarities of relationship between the pathogen and reactivity of the organism in infectious diseases. Principles of combination of antibiotics. Principles of monitoring the effectiveness and safety of anti-infectious therapy.

**1.6. Drugs used for the hemostasis correction.**

Pharmacodynamics of antihemorrhagic drugs, coagulants, stimulators and inhibitors adhesively-aggregation of platelets. Methods of monitoring effectiveness and safety of drugs used for the correction of hemostasis.

**2. Clinical pharmacology of drugs**

**2.1. Clinical pharmacology of anti-inflammatory and antiallergic drugs.**

Clinical pharmacology of steroidal and non-steroidal anti-inflammatory drugs. Antihistamine drugs. Allergic reactions to medicines. Drug anaphylactic shock: clinical manifestations, diagnosis, emergency medical care, prevention.

**2.2. Clinical pharmacology of antibacterial, antiviral and antifungal medicines**

Penicillin.
Cephalosporins.
Aminoglycosides.
Lincosamides.
Tetracyclines.
Glycopeptides.
Oksazalidinony.
Quinolone.
The fluorinated quinolones.
Sulfonamides.
Antiseptics.
Antifungal drugs.
Antiviral drugs.

**2.3 Analgesic drugs. Clinical pharmacology of local anesthetics. Medicinal lesions of the mucous membranes of the mouth. Medicinal herbs used in dentistry**

Narcotic analgesics and their antagonists. Non-opioid analgesic with central activity. Analgesics with a mixed mechanism of action. Clinical pharmacology of local anesthetics. Medicinal lesions of the oral mucosa. Medicinal herbs used in dentistry.

## EDUCATIONAL DISCIPLINE CURRICULAR CHART

| Section, topic # | Section (topic) name | Total number of auditory hours | | Self-studies | Form of control |
|---|---|---|---|---|---|
| | | lectures | practical | | |
| **1** | **GENERAL AND SPECIFIC QUESTIONS OF CLINICAL PHARMACOLOGY** | **12** | | **15** | |
| **1.1.** | The object and purpose of "Clinical Pharmacology", stages of development, the relationship with other academic disciplines. Basics of Evidence-Based Medicine | 2 | - | | control questioning, interviews |
| **1.2** | Clinical trials of drugs. The original and generic medicines. State regulation and clinical trials of medicines. Bioequivalence studies | 2 | - | | control questioning, interviews |
| **1.3** | Clinical pharmacokinetics, pharmacodynamics and their relationship. Physiological and age aspects of clinical pharmacology. Clinical pharmacogenetics. | 2 | - | | control questioning, interviews |
| **1.4** | Drug interactions. Basic principles of rational combined pharmacotherapy. Side effects of drugs. | 2 | - | | control questioning, interviews |
| **1.5** | Basics of rational antibiotic therapy | 2 | - | | control questioning, interviews |
| **1.6** | Drugs used for the hemostasis correction. | 2 | - | | control questioning, interviews |
| **2** | **CLINICAL PHARMACOLOGY OF DRUGS** | | **15** | | |
| **2.1** | Clinical pharmacology of anti-inflammatory and antiallergic drugs. | - | 5 | 5 | interviews, control |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | questioning, written classroom (home) practical exercises, essay, accounts of classroom practical exercises with oral defense |
| **2.2** | Clinical pharmacology of antibacterial, antiviral and antifungal medicines | - | 5 | 5 | interviews, control questioning, written classroom (home) practical exercises, essay, accounts of classroom practical exercises with oral defense |
| **2.3** | Analgesic drugs. Clinical pharmacology of local anesthetics. Medicinal lesions of the mucous membranes of the mouth. Medicinal herbs used in dentistry | - | 5 | 5 | interviews, control questioning, written classroom (home) practical exercises, essay, accounts of classroom practical exercises with oral defense, credits. |
| | **TOTAL HOURS** | **12** | **15** | **15** | |

# INFORMATION AND INSTRUCTIONAL UNIT

## LITERATURE

**Basic (relevant):**

1. Peter N. Bennett, Morris J. Brown. Clinical Pharmacology, 11e, 2012
2. Bertram Katzung, Anthony Trevor. Basic and Clinical Pharmacology 13 E , 2014
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics, Twelfth Edition, 2011

**Additional:**

4. Arthur J. Atkinson et al. Principles of Clinical Pharmacology. Third Edition
5. James M Ritter et al. A Textbook of Clinical Pharmacology and Therapeutics 5Ed. 2008
6. D.G. Grahame-Smith, J.K. Aronson. Oxford Textbook of Clinical Pharmacology and Drug Therapy. Hardcover – May, 2002

## LIST OF AVAILABLE DIAGNOSTIC TOOLS

The following forms are used for competences assessment:

1. Oral form:
- interviews;

2. Written form:
- control questioning;
- written classroom (home) practical exercises;
- essay;

3. Oral-written form:
- accounts of classroom practical exercises with oral defense;
- credits.

## LIST OF PRACTICAL SKILLS

- to be able to gather the pharmacological, and allergic history;
- be able to write prescriptions;
- be skilled in providing emergency medical care to patients with drug anaphylactic shock.

**PROTOCOL OF THE CURRICULUM APPROVAL**
**BY OTHER DEPARTMENTS**

| Title of the discipline requiring approval | Department | Amendments to the curriculum of the academic discipline | Decision of the department, which designed the curriculum (date, protocol # ) |
|---|---|---|---|
| 1. Pharmacology | Pharmacology | No suggestions | Approved: Protocol № 2 of 03.10 2017г. |

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Curriculum content, composition and accompanying documents comply with established requirements.

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