Thematic plan of seminars in the discipline «Methods of experimental study of the molecular basis of drug action»
for students of 2023 admission
under the educational program
33.05.01 Pharmacy,
Pharmacy profile
specialty,
full-time form of education
for the 2024-2025 academic year

№	Thematic blocks	Summary	Hours (academic)
1	**Relevance and problems of creating new drugs.**	History of the issue. Problems and methods of modern pharmacology. Main achievements in pharmacology in the XX-XXI centuries.	2
2	**Methods for searching for biologically active substances that affect various receptors.**	Biochemical classification of molecular targets in the modern pharmaceutical industry. Search for new drugs; active substances and lead compounds; agent-directed and target-directed search strategies. Agent-directed strategy: natural and synthetic antagonists; natural agonists and their analogues; examples of drugs developed using this strategy (penicillin, paclitaxel, insulin, etc.).	2
3	**Types of experimental screening of biological activity.**	Target-directed strategy: high-throughput (in vitro) and virtual screening (in silico). Biochemical, pharmacological screening. The role of medicinal chemistry in the process of developing new drugs.	2
4	**The concept of preclinical studies.**	The role of preclinical studies in the development of drugs, tasks of preclinical studies, types and methods of preclinical studies. Design of preclinical studies. Ethical aspects of preclinical studies.	2
5	**Biological test systems (*in vitro, ex vivo* and *in vivo*).**	Alternative research models and animal models. Cell cultures, bacteria, enzymes, isolated organs as test systems in preclinical studies. Bioethical standards when working with animals and the three R principles (replacement: choice and replacement; reduction: adequacy and standardization; refinement: reduction of distress, pain and suffering). Use and limitations in the use of primates.	2

		Basic principles of animal experiments.	
6	**Preclinical studies in accordance with good laboratory practice standards (GLP).**	Site, Equipment and Personnel. Standard Operating Procedures.	2
7	**General principles of studying the safety of drugs. Principles of studying the general toxic properties of drugs.**	Acute, subacute [subchronic] and chronic toxicity), local irritant effect. Study of cumulative properties of drugs.	2
8	**Principles of studying specific types of drug toxicity.**	Mutagenicity, reproductive toxicity, carcinogenic effect, allergenic effect, addictive effect, immunotoxic effect.	2
9	**Methods for studying the pharmacokinetics (PK) of drugs.**	Methods for studying the absorption, distribution, metabolism and excretion of drugs, as well as their bioavailability. Study of drug toxicokinetics. Evaluation of pharmacokinetic drug interactions.	2
10	**Extrapolation of experimental data from pharmacological and toxicological studies from animals to humans.**	Extrapolation factors. Dose determination for first-in-human drug trials. No apparent adverse effect level (NOAEL), minimal expected biological effect level (MABEL).	2
11	**Development of a dosage form. Promising mechanisms for drug delivery.**	Oral delivery mechanism: sustained-release formulations; use of excipients, liposomes and microspheres. Pulmonary delivery. Transdermal delivery: iontophoresis, sonophoresis. Polymer-assisted delivery. Controlled delivery and controlled target organ specificity. Use of liposomes as delivery vectors.	2
12	**Clinical trials (CT) as a stage of drug development.**	Objectives of clinical trials of medicinal products. Types of clinical trials. Phases of clinical trials. Rules for conducting clinical trials in accordance with the principles of good clinical practice (GCP).	2

13	**Design and implementation of clinical trials.**	Clinical trials: placebo effect, subject and observer effects, single and double blind experiment, randomization, crossover design. Key clinical trials documents (clinical trials protocol, informed consent). Phases I–IV clinical trials: number of patients, duration, parameters to be determined.	2
14	**Principles of evidence-based medicine.**	The Importance of Evidence-Based Medicine for Clinical Practice. The Concept of Meta-Analysis. Levels of Evidence. Sources of Information on Evidence-Based Medicine. Evidence-Based Medicine Databases.	2
15	**The procedure for registration of medicinal products in the Russian Federation.**	Stages of the drug registration procedure. Principles of drug examination. Accelerated registration procedure.	2
16	**The procedure for the development and registration of biologically active food supplements (BAA).**	Nutraceuticals and parapharmaceuticals. Methods of quality control and safety of dietary supplements. Safety indicators (microbiological, toxicological, etc.).	2
17	**Research of methods of treatment of drug poisoning in animals.**	Methods of studying the pharmacological interaction of poison and antidote in in vivo experiments. Methods of treating drug poisoning.	2
18	**Credit lesson.**	Summing up.	2
Total hours of seminar-type classes			36

Considered at meeting of the department of Pharmacology and bioinformatics

Protocol № 13 dated «04» april 2024

Head of the Department of Pharmacology and Bioinformatics, Academician of the Russian Academy of Sciences, Doctor of Medical Sciences, Professor A.A. Spasov