**AL-FARABI KAZAKH NATIONAL UNIVERSITY**

**Faculty of chemistry and chemical technology**

**Department of Chemistry and technology of organic substances, natural compounds and polymers**

**Final exam program for the discipline**

### Code SD1FP 4309 «Screening and preclinical trials of pharmaceuticals»

Educational program:

Code and name of the educational program

**6B07201 Technology of pharmaceutical production**

**Almaty 2021**

# Final exam programthe discipline is compiled by

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Reviewed and recommended at the meeting of the Chemistry and technology of organic substances, natural compounds and polymers

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Head of the department \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Mun G.A.

 (signature)

**Introduction**

**Exam formats:** Synchronous

**Exam form:** Written exam.

**Exam platform:** IS Univer.

**Exam type:** online

**Exam control** – Availability of automatic proctoring system or proctor.

**The exam lasts**: 3 hours.

**Types of questions**

**General theoretical question** - a student defines the keywords, describes the role and application in the discovery and development of new pharmaceuticals.

**Practice question** - a student describes the key properties of the subject and its application in drug development. It is necessary to answer how the properties of the studied subject effects on process or product.

**Topics for which ticket questions will be drawn up**

1. Pharmaceutical research and development challenges.
2. The main stages in the discovery of new drugs.
3. Development of new pharmaceuticals. Main stages, quality management systems and preclinical studies. Chemical methods in chemistry, manufacture and control.
4. The clinical trials and their phases. The importance of international regulatory documents (ICH and OECD) in the development of pharmaceuticals.

**Rules for conducting the exam form**

The process of passing a written exam by a student involves the automatic creation of an examination paper for a student, for which it is necessary to form a written answer by directly entering the text into the system. The students and teachers hold the exam on a schedule.

**Student instruction**

1. First, have to check the Internet connection on a computer device (laptop, tablet). The device must be provided with a charge at all times during the exam.

2. Open the Univer.kaznu.kz web portal through any browser, but preferably through Google Chrome.

3. Log in with your account. If you do not remember your username and password, you must contact your advisor-advisor before the start of the exam.

4. Go to the tab Bachelor, Master or Phd, depending on the level of study. Then activate the Exam Schedule functionality.

5. For those disciplines for which the exam time has come, the “Start written exam” command will appear (highlighted in red).

6. After clicking on the Start written exam link, a window will open where the student will see the questions on his examination paper. The exam lasts exactly 3 hours.

7. After the end of the time, the system will not accept written responses. Therefore, it is recommended to periodically save typed responses on the page until the time expires. The page displays a timer by which the student can navigate in time. If during the exam, the students lost their Internet connection or the student accidentally closed the page, then he must reconnect or re-enter the system by repeating steps 2 to 7. During the exam, the student can return to the system and continue answering his questions.

8. After completing the exam, your answers will be sent to the examiner for verification, who, after examining the Antiplagiat.ru system report with a detailed analysis of your textual answer, will evaluate your answer to the exam task.

9. Upon completion of the test, the examiner puts marks in the statement and you can see the results of the exam on the page of the current certification.

**Evaluation policy** *(a brief description of the assessment)*

The ticket contains 4 questions for each topic. Each question is worth 25 points. In case of incomplete disclosure of the question, where there will be only a description without analysis and examples, the answer is estimated at 15 points. With a brief analysis of the topic of the question, up to 20 points.

For all correct answers, the student receives 100 points.

***Recommended Literature Sources for Exam Preparation*** *(provides a list of literature on the discipline to prepare for the final control)*

1. Burger's Medicinal Chemistry, Drug Discovery and Development, Volumes 1 – 8. Wiley; 7th edition, 2010. 6356p.
2. Drug discovery handbook / edited by Shayne Gad. John Wiley & Sons, 2005. 1471p.
3. Preclinical Drug Development. Taylor & Francis Group, 2005. 570p.
4. Basic Principles of Drug Discovery and Development. Elsevier Science, 2015. 580p.
5. Drug Discovery and Clinical Research. Jaypee Brothers Publishers, 2011. 646p.
6. The Handbook of Medicinal Chemistry: Principles and Practice / edited by Andrew Davis, Simon E Ward. Royal Society of Chemistry, 2015. 753p.
7. Handbook of Laboratory Animal Science, Volume I. Essential Principles and Practices / edited by Jann Hau, Steven J. Schapiro. CRC Press, 2010. 780p.
8. OECD Principles on Good Laboratory Practice, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 1, OECD Publishing, Paris, 1998.

Web-resource:

1. Organisation for Economic Co-operation and Development – homepage: <https://www.oecd.org/>
2. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – homepage: <https://www.ich.org/>

About drug discovery online: https://www.drugdiscoveryonline.com/