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|  | **APPROVED**  **Vice-Rector for Research Activities, Professor**  **Zhusupov B.S. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **«\_\_\_\_»\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2018y.** |

**THE PROGRAM OF ENTRANCE EXAMINATION FOR PhD DOCTORAL DEGREE**

**SPECIALTY 6M074800 “PHARMACEUTICAL PRODUCTION TECHNOLOGY”**

**FOR 2018 - 2019 ACADEMIC YEAR**

**Almaty 2018y.**

The program was discussed and approved at the meeting of the department "Technologies of medicines and engineering disciplines" protocol No. \_\_\_, from "\_\_\_" \_\_\_\_\_\_\_\_ 2018y.

Head of the department

'Technology of medicines and engineering disciplines »

Doctor of pharmaceutical sciences, professor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Ustenova G.O.

The program was approved at a meeting of the Committee of Educational Programs of Postgraduate and Further Education,

Protocol No. \_\_\_\_, from "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_ 2018

Chairman of the CEP \_\_\_\_\_\_\_\_\_\_\_\_ Nurmakhanova Zh.M.

The program was approved at the meeting of the academic Council of KazNMU

Protocol no.\_\_\_\_, from "\_\_\_"\_\_\_\_\_\_\_\_\_\_\_\_2018 y.

Chairman, Professor \_\_\_\_\_\_\_\_\_\_\_\_\_Bayldinova K. Zh.

**Introduction**

The program covers general issues of industrial production, basic concepts and theoretical bases of discipline, state regulation of production of medicines and quality control, modern requirements for the production of medicines, technology of medicines, including the main provisions and requirements of good practices, problems and achievements.

Chemistry and technology of synthetic substances as the main subject in a number of special disciplines, determines the specificity of pharmaceutical analysis of medicines, their determining value in medical practice.

The program is developed taking into account the existing normative documentation for medicinal plant raw materials included in the State Register of Medicines authorized for using in medical practice and industrial production in Kazakhstan

The program addresses issues of chemical and pharmaceutical development, development of biological products, validation of technological processes within the requirements of good manufacturing practice.

The program outlines the current requirements for the production and standardization of medicines, including the main provisions and requirements of GMP.

**Purpose of the entrance examination:**

To evaluate the complex of competences (knowledge, skills, etc.) acquired by the undergraduate students in the process of training on the basic educational programs of the disciplines "Industrial technology of medicines", "Chemistry and Technology of Natural Substances", "Chemistry and Technology of Synthetic Substances" a certain type of professional activity.

**The tasks of the entrance examination:**

–То know about the achievements of pharmaceutical science and practice; the concept of pharmaceutical development at the modern stage;

* To know about the main regulatory documents related to the production, quality control, distribution, storage and use of medicines domestic and international standards (GMP, GLP, GPP), pharmacopoeia, guidelines and instructions approved by the Ministry of Healthcare of the Republic of Kazakhstan;
* To know the rules for ensuring aseptic conditions for the manufacture of medicines;
* To know the general principles of selecting and evaluating the quality and operation of process equipment (filtration plants, grinding apparatus and machines, sifting plants, sterilization units and apparatus, etc.);
* To know the basics of environmental safety of production and use of medicines, safety technology, labor protection regulations;
* To know about the algorithm of development, testing and registration of medicines, the methodology of optimization of existing medicines based on modern technologies and biopharmaceutical research in accordance with the international system of requirements and standards, and to have a holistic view of the problems of the modern pharmaceutical industry.
* To know the principles of pharmaceutical ethics and deontology;
* To know the biopharmaceutical aspects of drug development;
* To Know the basic requirements for the organization and structure of pharmaceutical production;
* To know the requirements for the organization of the technological process;
* To know the basics of obtaining biological products;
* To know the principles and parameters of validation.

**Form of carrying outentrance exams: The second stage of entrance exams (the 1st stage of entrance exams is testing according to the English language) consist of two periods:**

* 1. Testing in specialized subjects
* 2. Interviews
* The interview will be conducted in the form of an essay defense (Appendix 1).

**Contents of the disciplines for the entrance examination in the specialty of 6M074800 - "Pharmaceutical Production Technology"**

**"Industrial technology of medicines"**is one of the main disciplines that determines the content of practical activity of pharmaceutical process engineers, whose main tasks are: to study the theoretical bases for the manufacture of medicines of industrial production, applying the principles of organization of the technological process and compliance with the sanitary regime in accordance with international standards and standards; the development of new medicines in rational dosage forms and the improvement of existing prescriptions and technological schemes for obtaining on the basis of biopharmaceutical research using modern equipment for their production, etc.

At the current stage, the issues of creating long-acting and direct-acting dosage forms with controlled release of medicinal substances are topical; development of new types of packaging; search for new excipients, improve the quality control of dosage forms; conducting biopharmaceutical research using "in vivo" and "in vitro" methods.

Rules for the organization of production and quality control of medicines, provided by GPP, GMP, GLP, GCP. Principles of GMP (terminology, quality assurance, personnel, buildings and premises, equipment, production process, technical control department, validation, requirements for the production of finished medicines).

**Pedagogy:** Basic concepts, methodology, objects and history of development. Pedagogy of higher education. Basic directions and tendencies of development of higher education in the modern world. New paradigm of education. Higher education in the Republic of Kazakhstan: the main stages of reform, integration into the world educational space. Essence and structure of pedagogical activity. Personality, professional abilities and competence of the teacher. Theory of teaching in higher education (didactics): the essence and structure of vocational training, driving forces and principles of learning. Educational work in higher education: the essence and main directions. Supervision. Modern educational technologies. Active forms and methods of teaching. Organization of the educational process on the basis of the credit system of training: organization of the CDS, pedagogical control, compilation of educational materials. Quality management system of education.

**The list of questions of the discipline "Fundamental basics for the development of medicinal preparations''**

1. Current state and prospects for the development of pharmaceutical technology. The development of pharmaceutical technology in the Republic of Kazakhstan.

2. Comparative characteristics for extemporal manufacture of medicines, small-scale and industrial production. Prospects for the development of each ofthese areas.

3. State regulation of production and quality control of medicines. Legislative basis for the manufacture of medicines.International and state (national) requirements for the quality of medicines.Rationing for medicinal products.

4. Organization on the production of medicines in accordance with modern requirements of GMP.

5. Modern achievements in the technology of medicinal forms. Generations of dosage forms.Modern drug delivery systems and carriers of biologically active substances.Micro-carriers, nano-carriers, therapeutic systems.

6. The main methodological approaches to the creation and design of therapeutic systems (intraocular, transdermal, implantation, etc.)

7. Biopharmacy is a modern methodology and the basis for creating modern medicines. The history of the emergence and development of biopharmacy. Concepts: biopharmacy, pharmacokinetics, pharmacodynamics, bioequivalence, therapeutic non-equivalence, bioavailability (absolute, relative).

8. Research, development and manufacture of medicinal products in accordance with international requirements and national standards: GхP.

9. General principles for the development of regulatory documentation, regulating conditions, manufacturing technology and quality control of medicinal products. Types of technological regulations.

10. Modern theories of creating stable medicines. Shelf life, shelf life and period of medicine use.Physicochemical processes and stabilization of medicinal products (physico-chemical, structural-mechanical and antimicrobial stability).

11. The main technological processes in pharmaceutical technology. Mechanical, mass-exchange and hydromechanical processes, their influence on the quality indicators of the final product.

12. Grinding of solid materials, raw materials with a cellular structure, grinding in liquid and viscous media. The influence of the grinding process on the technology of obtaining medicines and their quality.Methods for the preparation of microheterogeneous mixtures.Dispersing in liquid media.

13. Cleaning solutions in pharmaceutical technology. Filtration.Modern methods of controlling mechanical inclusions in dosage forms.

14. Mass exchange processes. Extraction. Capillary phenomena, swelling, dissolution, desorption, osmosis, dialysis, ultrafiltration, molecular diffusion and convection processes.

15. Adsorption and ion exchange. Crystallization.Extraction in the liquid-liquid system, modern aspects of utilize in pharmaceutical technology.

16. Theory of solubilization. Surface-active substances used as solubilizes. Hydrophilic-lipophilic balance.Critical concentration of micelle formation. Practical application of solubilizes in pharmaceutical technology.

17. Modern types of packaging materials and packaging products. Regulation of requirements for packaging materials. Effects of packaging on stability during the storage, transport and utilize of medicines. Justification of rational packaging choice.

18. Justification of the choice of methods for quality control of medicinal products. Development and validation of quality control methods for medicines.

19. Validation of technological processes. Validation of technological processes at the development stage.

20. Requirements for the structure and volume of pharmaceutical development.

21. Development of technology for the production of tablets.

22. Development of technology for production of suppositories.

23. Development of technology for the production of liposomal forms of drugs.

24. Development of technology for the production of capsule forms of drugs.

25. Development of technology for the production of soft forms of medicinal products.

26. Technology transfer in pharmaceutical development.

27. Preclinical research. Features of preclinical researches on medicines.

28. Basic registration procedures.

29. Rules for evaluating the bioequivalence of medicines.

30. Types of destruction of medicines (chemical, physicochemical, microbiological, etc.). Accounting to the nature of hydrolytic, oxidation-reduction, thermodynamic, enzymatic and other processes in the development of stable medicines in various dosage forms.

31. Isolation and purification of biologically active substances. Methods and equipment for cleaning extracts, separating the sum of substances, isolating individual substances.

32. Analysis for the production formulation. The production formula.Material balance.

33. Quality control of raw materials (pharmaceutical substances) in the production of medicines, intermediates and control points at the stages of production of the medicinal product.

34. Screening of promising biologically active compounds from various sources for using in medicine and pharmacy.

35. Development of technology for the production of soft forms of drugs.

36. Validation of technological processes. Validation of technological processes at the development stage

37. The transfer of technology in pharmaceutical development

38. Description of the process in the development

39. Preclinical study. Features of preclinical studies of drugs.

40. Basic registration procedures.

41. Rules for evaluation of bioequivalence of medicines.

42. Types of destruction of drugs (chemical, physico-chemical, microbiological, etc.). Taking into account the nature of hydrolytic, oxidation-reduction, thermodynamic, enzymatic and other processes in the development of stable drugs in various dosage forms.

43. Isolation and purification of biologically active substances. Methods and equipment for purification of extracts, separation of the sum of substances, isolation of individual substances.

44. Mechanization of technological processes in the condition of small-scale production of small-scale mechanization (devices, devices, etc.).

45. Features of production of drugs in conditions of small-scale production. Quality of medicines in the conditions of technology transfer. Pilot production of medicines.

46. Analysis of the production formulation. Production formula. Material balance.

47. Quality control of raw materials (pharmaceutical substances) in the production of medicines.

48. Quality control of intermediates and control points at the stages of drug production.

49. Scientific substantiation of storage and transportation of various drugs.

50. Screening of promising biologically active compounds from various sources for use in medicine and pharmacy.

**List of questions for discipline "Pedagogy"**

1. Pedagogy as a science: the object and subject of pedagogy.

2. The tasks of pedagogical science.

3. The system of pedagogical sciences.

4. Relationship of pedagogical science with other sciences.

5. The main categories of pedagogy.

6. The main guidelines for the development of the educational system of the Republic of Kazakhstan at the present stage.

7. The state and problems of education in Kazakhstan at the present stage.

8. Indicators of the quality of education.

9. Reforming the education system in line with world standards.

10. International criteria for education.

11. Government’s program for the development of education in the Republic of Kazakhstan for 2011-2020.

12. Experience of introduction of distance educational technologies in Kazakhstan

13. Personality as an object of education and training

14. General theory of personality development.

15. The theory of age-related personality development.

16. Personality development and its factors.

17. The concept of methods of education.

18. Classification of methods of education.

19. Characteristics of methods of education.

20. The concept of means of education.

21. Classification of means of education, their characteristics.

22. Didactics as a theory of education and training

23. The subject and tasks of didactics.

24. Basic didactic concepts.

25. Formation of the modern didactic system

26. The learning process. The concept and essence of learning.

27. The learning process as an integral system.

28. Cyclicity of the learning process.

29. Learning functions.

30. Teaching as a teacher's activity.

31. Teaching as the cognitive activity of the learner.

32. Teaching technology. Developmental training.

33. Verification and evaluation of learning outcomes, diagnosis of training.

34. The essence of control of teaching as a didactic concept.

35. Methods and forms of control. Assessment of students' knowledge.

36. Diagnostics of training.

37. Testing of achievements and development.

38. The concept and essence of the content of education.

39. Sources and factors of formation of the content of education.

40. Government’s standard of education.

41. The concept and essence of the method and reception of training.

42. Classification of teaching methods.

43. The concept of a means of teaching. Classification of teaching means, their characteristics.

44. Forms of training organization and their development in didactics.

45. Forms of organization of education in higher education.

46. ​​Educational innovations. Definition of the concepts "pedagogical system", "innovations in the pedagogical system".

47. Innovative pedagogy, innovative educational institutions. Optimization of the pedagogical system.

48. Pedagogical art and skill. The concept of "Pedagogical Art".

49. Essence and basic components of pedagogical art.

50. The essence and spheres of the manifestation of pedagogical skill.

**Recommended literatures**

**Basic:**

1. В.И. Чуешов, Е.В. Гладух, И.В. Сайко. Технология лекарств промышленного производства. Ч. 1. –Винница: Нова книга, 2014. -696 с.
2. В.И. Чуешов, Е.В. Гладух, И.В. Сайко. Технология лекарств промышленного производства. Ч. 2. –Винница: Нова книга, 2014. -664 с.
3. Нормирование фармацевтического производства, Обеспечение качества продукции, В.В. Береговых, А.П. Мешковский Из-во ЗАО Информационно-издательское агентство «Ремедиум», Москва,2004.-524с.

**Additional:**

1. Государственная Фармакопея Республики Казахстан – Т. 1. – Алматы: – Издательский дом «Жибекжолы», 2008г – 592 с.

2. Государственная Фармакопея Республики Казахстан – Т. 2. – Алматы: – Издательский дом «Жибекжолы», 2009г – 792 с.

3. Государственная Фармакопея Республики Казахстан – Т. 3. – Алматы: – Издательский дом «Жибекжолы», 2014г – 869 с**.**

4**.** Быковский С.Н. Фармацевтическая разработка: концепция и практические рекомендации. Изд-во Перо, 2015. – 472 с.

5. Ш.К. Гэд. Производство лекарственных средств. Контроль качества и регулирование. ЦОП «Профессия»., 2013. – 960 с.

6. А.Т. Солдатенков, Н.М. Колядина, И.В. Шендрик. Основы органической химии лекарственных веществ - М: Химия, 2001.

7. К. Хломберг, Б. Йенссон, Б. Кронберг, Б. Линдман Поверхностно-активные вещества и полимеры, М.:Бином. Лаборатория знаний, 2007г. —512с.

5. Подласый И.П. Педагогика Кн.1-М., 2010, С.9-42;

6. Педагогика. Учебник/ Сластенин В.В., Исаев И.Ф./ Шиянов Е.Н., 2007.

7. Педагогика /Под ред. П.И.Пидкасистого- М., 2012.

8.Кунанбаева С.С. «Болонская конвенция и международное научнообразовательное пространство» – круглый стол, Алматы, 2017

9. Афанасьев А.Н., Болонский процесс в Германии / А. Н. Афанасьев // Высшее образование сегодня. 2013. № 5. С.54-57

10. Беркимбаева Ш. Высшая школа: курсом обновления. 2004

11. Рахимбек Х. М. Реформирование высшего образования в Казахстане и Болонский процесс.2012

12. Пуйман С.А. Педагогика. Основные положения курса. Минск, 2012, С. 17 – 33;

13. Воронов В.В. Педагогика школы в двух словах (Конспект - пособие) – М., 2009, С. 27 –31.

14. Коротов В.М. Введение в общую теорию развития личность: Лекции.- М, 2014.

15. Загвязинский В.И., Атаханов Р. Методология и методы психолого-педагогического исследования – М., 2011-207с.

16. Селиванов В.С. Основы общей педагогики: Теория и методика воспитания. М.: Академия. 2014. - 336с.

17. 100 экзаменационных ответов по педагогике – Ростов н/Д, 2015.

18. Зверева Н.М. Практическая дидактика для учителя: Учебное пособие. - М., 2015

19. Загвязинский В.И. Теория обучения: современная интерпретация. М., 2013

20. Педагогика / Под ред. П.И.Пидкасистого – М.,2012, С. 50-40;

Appendix 1

Annotation

for the planned dissertation researches of applicant for doctoral studies

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(Full nameof the Applicant)

The title of the scientific work:

**Domestic scientific consultant:**

Academic degree, position, full name, signature

**Foreign scientific adviser:**

Academic degree, Full name

**Almaty 2018y.**

Relevance of the topic

Purpose and objectives of the study

Research methodology (study design, research methods, research objects, prospective scope of research)

Scientific novelty

Theoretical and practical significance

Expected results

List of used literature

Appendix 2

Rules for evaluating the annotation:

The maximum score for evaluating the annotation is 100 points.

Each section of the annotation is evaluated separately for the point system, the maximum score is 20 points.

Check list

EVALUATION OF THE ANNOTATION OF THE DISSERTATION RESEARCH

(Full name of the applicant)

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| **Sections of annotation** | **Number of points** |
| Section 1. Relevance of the selected research topic |  |
| Section 2. Purpose, research objectives |  |
| Section 3. Evaluation of the design of the study |  |
| Section 4. Scientific novelty, theoretical and practical significance of the expected results of the study |  |
| Section 5. Achievability of scientific results |  |
| **Sum of points** |  |

Comments, dissenting opinion of a commission member

Member of the commission

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Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_