MEDICAL UNIVERSITY OF KARAGANDA

PROGRAM OF ENTRANCE EXAMINATION
DOCTORED SPECIALTY
6D074800 - PHARMACEUTICAL MANUFACTURE TECHNOLOGY

KARAGANDA 2019

The program of entrance examinations for the doctoral studies of the specialty 6D074800 - “Technology of pharmaceutical production” is based on the standard curriculum for the specialty “technology of pharmaceutical production”.

The developer of the entrance exam program - Department of Pharmaceutical Disciplines and Chemistry

1. The purpose of the entrance exam is to identify the degree of preparedness of entering the PhD-doctoral program for mastering the educational program for preparing students of doctoral students in the specialty "technology of pharmaceutical production" in accordance with the requirements of the state general educational standard.

2. Tasks:
The entrance exam program includes the main topics of the disciplines of the Master's program in the specialty "technology of pharmaceutical production":
History and philosophy of science, Fundamental bases of drug development and solves the following tasks:
1. Assessment of the degree of theoretical development of the educational professional program with the specialization "technology of pharmaceutical production"
2. Assessment of the degree of theoretical development of related disciplines of the educational professional program of the specialty "technology of pharmaceutical production"
3. The content of the program of the entrance exam for the educational program "Doctoral degree" in the specialty "technology of pharmaceutical production".

The entrance exam program includes questions of the main sections of the disciplines:

3. The content of the discipline "Fundamental bases of drug development"

Pharmaceutical science, its applied value for drug technology. The stage of development of the composition and technology of medicines.
Chemical engineering Development of technology for the synthesis of substances at the stage of pharmaceutical development. Proof of active ingredient structure, possible isomers. The study of the physico-chemical characteristics of the substance. Impurity profile. Standardization. Development of production methods (synthesis, isolation, modification, etc.). Development of laboratory regulations. Development of technology for pilot production (pilot batch) and its optimization
Development of industrial technologies for the production of substances. Technological equipment requirements. Acceptance test reports. The concepts of FAT, SAT, URQ.
Pharmaceutical development. Development of production technology of finished dosage forms.
Technology of pills. Modern types of preformed forms. Development of suppository production technology. Technological and instrumental schemes. Standardization of pharmaceutical products. Development of technology for the production of liposomal drugs. Capsule technology Development of soft forms technology. Functional characteristics and technological purpose of excipients in the development of drugs. Physical, chemical classes of substances.
Functional characteristics, requirements for modern auxiliary substances. The study of compatibility with excipients, physico-chemical properties of variants of compositions. LF prolonged action, controlled release. Injection LF, infusion solutions with prolonged action, classification, technology features.
Directed transport of drugs, technological approaches to the creation of systems of directional transport. Creation of the composition and technology development of drugs. Selection of the optimal dosage form and optimal PL technology. The creation of new generation drugs based on the achievements of biotechnology and physical -
chemical biology. Nanotechnology in pharmacy.
Study of the stability of the dosage form. Tests of stability, the establishment of a re-control period, shelf life, storage conditions of pharmaceutical substances. The concept of free radical oxidation. Classification of modern antioxidants, obtaining.
Biopharmaceutical drug research.
Innovative ways to create drugs based on the use of genomics, proteomics and bioinformatics.

The content of the discipline "History and philosophy of science"

Philosophy and methodology of science as a branch of philosophical knowledge. The main stages of the historical dynamics of science. The structure of scientific knowledge. Fundamentals of science. Scientific picture of the world. Dynamics of science as a process of obtaining new knowledge. The concept of scientific theory. Types of scientific theories are their conceptual features. The problem of the distinction between science and non-science. Criteria for verification and fraud. The causes and forms of errors in knowledge. Features of the modern stage of development of science. Global scientific revolutions and the main types of scientific rationality. Science as a social institution.

4. Approximate list of questions for the entrance exam

1. The development of pharmaceutical technology at the present stage.
2. Biopharmaceutical research in pharmaceutical technology.
3. Pharmaceutical factors that determine the therapeutic efficacy of drugs.
4. Bioavailability of active substances from the dosage forms of the new generation, comparative characteristics.
5. Study of pharmacokinetics of dosage forms (in vivo and in vitro methods).
6. Prolonged dosage forms. Methods of prolongation.
7. Enteral osmotic systems for the release of drugs in the gastrointestinal tract (oral or rectal)
8. Parenteral osmotic systems - vaginal, ophthalmologic (lamina - plate)
9. Intracavitary therapeutic systems (intrauterine, rectal, etc.)
10. Silicone implant therapy systems.
11. Transdermal osmotic systems.
12. Implantable dosage forms, range, advantages and disadvantages. Therapeutic systems, technology.
13. Technological aspects of solid dosage forms of prolonged action.
14. Tank dosage forms.
15. Solid dosage forms of prolonged action. Matrix tablets.
16. Solid dosage forms with prolonged action. Spansuly.
17. Problems of providing targeted transport of drugs in pharmaceutical technology, solutions.
18. Therapeutic systems with targeted delivery of drugs.
19. First generation drug carriers (microcapsules, microspheres). A brief comparative description.
20. Microcapsules, characteristics, methods of microencapsulation.
21. Physical methods of microcapsulation.
22. Physico-chemical methods of microencapsulation.
23. Chemical methods of microencapsulation.
24. Dosage forms of microcapsules.
25. The main methods of obtaining microcapsules and instrumentation.
26. Prospects for the development of microencapsulation.
27. Microspheres. Characteristic. Technology of receipt.
28. Media carriers of the second generation (nanocapsules, liposomes).
29. Nano-carriers. Characteristic. Types of nanoparticles.
30. Liposomes, liposomal forms of drugs.
31. Characterization of liposomes, methods of obtaining.
32. Third generation carriers of drugs (antibodies, glycoproteins).
33. Antibodies. Glycoproteins as carriers for LV. Characteristic.
34. Magnetically controlled systems.
35. Long-acting cardiotropic drugs for the treatment and prevention of cardiovascular diseases.
36. Long-acting drugs (for removing and preventing the absorption of radionuclides, for the treatment of alcoholism; wounds and burns, etc.)
37. New dosage forms of drugs for the treatment and prevention of AIDS.

38. Monoclonal antibodies to provide targeted transport of drugs.
39. Obtaining monoclonal antibodies.
40. Age-related drugs. Features of technology.
41. Modern dosage forms used in pediatrics
42. Modern dosage forms used in geriatrics
43. Special dosage forms. Homeopathic medicine.
44. The use of modern pharmaceutical technology in the production of cosmetic products.
45. Modern ophthalmic dosage forms. Soluble inserts. Biopharmaceutical evaluation.
46. Modern ophthalmic dosage forms. Insoluble inserts. Biopharmaceutical evaluation.
47. Biosoluble ophthalmic inserts. Biopharmaceutical evaluation.
48. Immobilization of drugs on various carriers, immobilization methods.

LITERATURE:

Recommended literature on the discipline "History and Philosophy of Science"

1. Moiseev V.I. Philosophy of science. Philosophical problems of biology and medicine: a tutorial / V.I. Moiseev. - M.: GEOTAR-Media, 2015. - 592 p.
2. Khrustalev Yu.M. Philosophy of science and medicine: electr. textbook / Yu.M. Khrustalev - M .: GEOTAR-Media, 2009
3. Moiseev V.I. Philosophy of science: philosophical problems of biology and medicine: a textbook for universities, V.I. Moiseev - M .: GEOTAR-Media, 2008 -560 s,
4. Khrustalev Yu.M. Philosophy of science and medicine: a textbook for graduate students and applicants / Yu.M. Khrustalev, G.I. Tsaregorodtsev - M .: GEOTAR-Media, 2007.- 512 p.
5. Trofimov V.K. V.K., Trofimov. Philosophy, history and methodology of science: study guide Izhevsk, 2014. Electronic resource. Available at http://www.izhgsha.ra/img/UserFiles/File/Electron%20izdaniya/Philosofiya/Trofimov_UchPosob_2014.pdf
6. V.G. Gorokhov History and philosophy of science. Tutorial. Electronic resource. Available at: http: //newuc.jinr.ra/img_sections/file/Aspirant/Gprochov/GorokhovKonzeptziiFN2.pdf6.

Recommended literature on the subject "Fundamental bases of drug development"

1. Innovative technologies and equipment for pharmaceutical production. / Ed. N.V. Menshutina. In 2 t. T.1. M.: BINOM, 2012. 328s.
2. Innovative technologies and equipment for pharmaceutical production. / Ed. N.V. Menshutina. In 2 t. T.2. M.: BINOM, 2013. 480s.
3. State Pharmacopoeia of the Republic of Kazakhstan. –Tom1 - Almaty. - Publishing house: “Zhibek Zholy” .– 2008.– 592 p.
4. State Pharmacopoeia of the Republic of Kazakhstan. Volume 2. - Almaty. Publishing House: Zhibek Zholy. 2009. –792 seconds
5. Gavrilov A.S. Pharmaceutical technology. Production of drugs: Textbook / A. S. Gavrilov, 2010, GEOTAR-Media. - 624 s.
6. Ustenova, G. O. The use of supercritical carbon dioxide extraction in pharmaceutical technology: monograph / G. O. Ustenova. - Almaty: Evero, 2012. - 128 p.
7. V.A.Bykov et al. Pharmaceutical technology: a guide to laboratory work: studies. allowance - M .: GEOTAR-Media, 2010. - 304 p.

8. Modified release dosage forms and drug delivery systems. Features pharmacokinetics and clinical efficacy. / M. V. Leonova, Yu. B. Belousov. M.: Litterra, 2011. 656 p.
9. Almagambetov K.Kh. Biotechnology / K. Kh. Almagambetov, 2011. - 270 p.
10. Orekhov S.N. Pharmaceutical biotechnology: a guide to practical exercises: studies. manual / S.N. Orekhov, 2009, GEOTAR-Media. - 384 s.
11. Pletenyova T.V. Quality control of drugs: a textbook / TV. Pletenyova, E. V. Uspenskaya, L. I. Muradova; ed. T. V. Pletenev. - M.: GEOTAR-Media, 2015. - 560
12. Maksimkina E.A. Standardization and quality assurance of medicines: studies. manual / E. A. Maksimkina, G. I. Minazova, N. V. Chukreeva, 2008, Medicine. - 256 s.