

Catalog of elective disciplines

1. **Department:** Drug Technology and Pharmacognosy.
2. **The level of training:** Doctoral studies.
3. **Educational program:** Pharmacy.
4. **Year of study:** 1
5. **Name of the elective discipline:** Organization of the production of medicines according to GMP.
6. **Number of credits:** 3
7. **The purpose of the discipline:** Formation of ideas on the organization of the production of medicines according to GMP.
8. **Content of the discipline:** Good manufacturing practice is a part of a quality assurance system that ensures that products are consistently manufactured and controlled according to quality standards appropriate to their intended purpose, as well as in accordance with the requirements of the registration dossier or specification for these products. Good manufacturing practices are relevant to both production and quality control in the manufacture of medicines.
9. **Objectives:** GMP requirements for premises and equipment; – requirements for sterile production; – requirements for the design of clean areas; GMP requirements for personnel to work in clean areas; – requirements sanitary treatment of clean areas; – requirements of Good manufacturing practice for conducting internal production control.
10. **Justification of the choice of the discipline:** The discipline "Organization of the production of medicinal products according to GMP" is presented for the first time and is mainly due to the need for further professional development and certification of specialists at the stage of postgraduate education. Good manufacturing practices are part of a quality assurance system that ensures that products are continuously manufactured and monitored according to quality standards appropriate to their intended purpose, as well as in accordance with the requirements of the registration dossier or specification for this product. Quality assurance is a broad concept that encompasses all the parameters that individually or collectively affect product quality. This is the result of all measures aimed at achieving a given level of quality of medicines. Good manufacturing practices are part of a Quality Assurance System that ensures that products are consistently manufactured and controlled in accordance with the requirements of the product specification. Good manufacturing practices are relevant to both production and quality control in the manufacture of medicines.
11. **Learning outcomes:**

LO 1.	demonstrates knowledge of the requirements of GXP and the requirements of international GMP standards;
LO 2.	monitors the life cycle of a medicinal product in accordance with the requirements of the international standard GMP;
LO 3.	expresses his own judgments on research methodologies; ability to logical and reasoned analysis, public speaking, and discussion;
LO 4.	is able to use information and computer technologies in the field of professional activity; is able to transfer his own knowledge and skills; presents his own judgments, forms out in the form of a presentation, a project and presents the results of scientific research at scientific conferences, etc.
LO 5.	develops his intellectual and general cultural level; is capable of self-education, introspection, self-study; is capable of perceiving information, analyzing, setting goals and choosing ways to achieve it, and communicating; has the skills of public speaking with the presentation of his own judgments, analysis and synthesis of information.
LO 6.	knows the methodology of scientific research in the field of GMP drug production, knows the principles of conducting research in accordance with national and international GMP standards.

12. Prerequisites: Industrial technology of medicines, Good pharmaceutical practice.

13. Post-requirements: Research practice.

14. Literature

Main:

1. Biopharmaceutical zhane darilik preparattards biopharmaceutical zertteu: oku kuraly / B. A. Sagyndykova, R. M. Anarbayeva. - Karaganda : Medet Group, 2021. - 172 b.
2. Pharmaceutical technology. Industrial production of medicines. Vol. 1 : textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2020. 352 p. : ill. (Cipher 615.45/F 247-947861)
3. Pharmaceutical technology. Industrial production of medicines. Vol. 2 : textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2022. 448 p. : ill. (Cipher 615.45/F 247-862915)
4. Sagyndykova, B. A. Darilerdin darikhanalyk tehnologiyasi: okulyk / B. A. Sagyndykova, R. M. Anarbayeva. - Karaganda : Medet Group, 2021. - 556 bet.
5. Arystanova T.A. Pharmaceutical quality system and proper pharmaceutical practices : a textbook / T. A. Arystanova, J. M. Arystanov. Karagandy : Medet Group, 2021. 150 p. (Code 615.014/A 895-319357)
6. 6. Pharmaceutical technology. Technology of dosage forms : textbook / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2018. 656 p. : ill. (Cipher 615.45/F 247-542849)

Supplementary:

1. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 3: monograph / Ministry of Health of the Republic of Kazakhstan. - 3rd ed. ; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. - Almaty : Publishing house "Zhibekzholy", 2014. - 872 p.
2. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 1: monograph / Ministry of Health of the Republic of Kazakhstan.-3rd ed.; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. Almaty: Publishing house "Zhibekzholy",2015.720p.
3. Gavrilov, A. S. Pharmaceutical technology. Manufacturing of medicinal preparations: textbook / 3rd ed., revised Ministry of Education and Science of the Russian Federation. Rec. GBOU VPO "First Moscow State Medical University I. M. Sechenov University. Moscow : GEOTAR - Media, 2022. 864
4. Gavrilov, A. S. Pharmaceutical technology. Manufacturing of medicines : textbook - 2nd ed., revised ; Ministry of Education and Science of the Russian Federation. Rec. GBOU VPO "First Moscow State Medical University I. M. Sechenov University. Moscow : GEOTAR - Media, 2016. 760 p. - 15 copies.
5. Loyd, V. Allen. Pharmaceutical technology. Manufacturing of medicines [Text] : textbook. the manual / V. Allen. Loyd, A. S. Gavrilov ; Ministry of Education and Science of the Russian Federation. Moscow : GEOTAR - Media, 2014. 512 p.

Electronic resources:

1. Electronic resources of YUKMA JSC
2. The YUKMA Electronic Library - <https://e-lib.skma.edu.kz/genres>
3. Republican Interuniversity Electronic Library (RMEB) – <http://rmebrk.kz/>
4. Aknurpress Digital Library - <https://www.aknurpress.kz/>
5. The Epigraph Electronic Library - <http://www.elib.kz/>
6. Epigraf - multimedia textbook portal <https://mbook.kz/ru/index/>
7. EBS IPR SMART <https://www.iprbookshop.ru/auth>
8. Information and legal system "Zan" - <https://zan.kz/ru>
9. Medline Ultimate EBSSO
10. eBook Medical Collection EBSSO
11. Scopus - <https://www.scopus.com/>

1. **Department:** organization and management of the pharmaceutical business
2. **Level of education:** scientific and pedagogical PhD programme
3. **Educational programme:** D140-Pharmacy
4. **Course:** 1
5. **Name of the elective discipline:** The concept of marketing research in pharmacy
6. **Number of credits:** 4 credits
7. **Purpose:** To acquire professional competencies necessary for the systematic search, collection, analysis, interpretation and presentation of results in the process of research work.
8. **The content of the discipline:** in order to obtain competitive advantages, participants in the pharmaceutical market need objective information and analytical materials obtained as a result of marketing research. In this regard, marketing research is necessary for the successful operation of any enterprise, since the use of their results will reduce the degree of inevitable risk, reasonably develop corporate (portfolio, growth, competitive), functional and instrumental strategies.
9. **Tasks:**
 - to study the place of marketing research in the field of drug circulation;
 - to acquire systematic knowledge of doctoral students about the methodology of marketing research;
 - to teach how to carry out pharmaceutical market research;
 - to acquire practical skills in determining the competitiveness of pharmaceutical organizations;
 - to teach how to use information based on IT-technologies in the field of professional activity.

10. Rationale for the choice of discipline:

The development of the sphere of drug circulation in a market economy involves the use of marketing research methods to study the behavior of consumers, intermediaries, suppliers, competitors, and, in general, the entire market situation. In order to strengthen competitive advantages, pharmaceutical market participants cannot do without objective information and analytical materials obtained as a result of marketing research. In this regard, marketing research is necessary for the successful operation of any enterprise, since the use of their results will reduce the degree of inevitable risk, reasonably develop corporate (portfolio, growth, competitive), functional and instrumental strategies.

11. Learning outcomes (competencies)

Knowledge (cognitive sphere)	Skills and abilities (psychomotor sphere)	Personal and professional competencies (relationships)
demonstrates a systematic understanding of conceptual approaches to marketing research based on the International and European Codes of Marketing Research , the importance of marketing research and information support of marketing in the field of medicines circulation.	plans marketing research of the pharmaceutical market, determining the sample size and justifying the choice of marketing research methods, developing the design of a drug consumer research based on the differentiation of the marketing environment; determines the market capacity of medicines and medical devices, types of segmentation based on the study of the marketing environment of the enterprise and the pharmaceutical market using modern methods of marketing analysis, arguing	possesses the skills of public speaking with the presentation of their own judgments, analysis and synthesis of information, building partnerships, trusting relationships with colleagues and healthcare workers, demonstrating multiculturalism and openness in work; engages in professional growth by demonstrating introspection skills, teaching experience at the higher education level, searching information in databases for writing research papers, developing ideas, systematizing and interpreting scientific research results based on critical thinking.

	own conclusions, evaluating and interpreting the results of scientific research, explaining the observed facts and phenomena, their cause-and-effect relationships, presenting and publishing the results of scientific research, introducing scientific achievements in the pharmaceutical industry; conducts a critical analysis and evaluation of marketing information, demand, competitors and competitiveness of a pharmaceutical and pharmacy enterprise, choosing methods for predicting the need for certain groups of medicines, methods for studying the range of pharmaceutical products.	
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12. Prerequisites: management and marketing in pharmaceutical companies.

13. Postrequisites: research practice.

14. Literature

Main:

1. Arystanov Zh.M., Akhelova Sh.L., Zulpikharova A.T. Management and economics of pharmacy with the basics of management and marketing: Textbook. "Celestial Systems" 2021
2. Arystanov, J. M. Management and marketing in pharmacy: a textbook / J. M. Arystanov, A. T. Tokseitova. - Almaty: Evero, 2016. – 532 p.
3. Shertaeva, K. D., Mamytaeva K.J. Pharmaceutical marketing: okulyk / KR DS ADM.Shymkent : [B. I.], 2016. - 152 B. S.
4. Medical and pharmaceutical merchandising [Text] : textbook / K. D. Shestakova [et.al .]. -, 2022. - 108 p.

Additional:

1. Management and economics of pharmacy: textbook / ed. I.A. Narkevich. – M.: GEOTAR-Media, 2017. – 928 p.

Electronic resources:

1. UMKD is created on the educational portal ukma.kz
2. website of the Academy of BiblioTech and Information Center lib.ukma.kz
3. Media Library YUKMA <https://media.skma.edu.kz/>
4. Digital Library" Akpgress " www.aknurpress.kz go to registration and apply the SDH-28 promo code
- 5th <http://aknurpress.kz/login> promo code SDN-28 base Dann Scopus <https://www.scopus.com/home.uri>
6. base dung Springer <https://link.springer.com/>
7. SKMA repository <http://lib.ukma.kz/repository/>

8. Republican Interuniversity Electronic Library <http://rmebrk.kz/>
9. base of normative legal acts " Law " <https://zan.kz/ru>
10. Information System" paragraph Medicine " <https://online.zakon.kz/Medicine/>

1 . Department: organization and management of pharmaceutical business

2. Level of education: scientific and pedagogical PhD programme

3. Educational programme: D 140-Pharmacy

4. Course: 1

5. Name of the elective discipline: Management bases of good practices in pharmacy

6. Number of credits: 3 credits

7. Purpose: Formation of professional and communication competencies for the application of the basic principles, categories, methods and tools of quality management in modern pharmaceutical organizations in the market.

8. The content of the discipline: a good practice management system is designed to ensure the proper quality of medicines through strict adherence to standards at every stage of their life cycle. The rules of Good Pharmaceutical Practices are based on the process approach, which includes: classification of processes; determination of the sequence, interconnection, interaction of processes; definition of criteria and methods for evaluating the functioning of processes; description of processes; process analysis and improvement

9. Tasks:

- to form systemic knowledge on the development of documentation for the organization's quality management system in accordance with the requirements of ISO 9000 standards when building a system and preparing an enterprise for certification;
- to acquire skills in applying international standards in the process of creating and certifying a quality management system at a pharmaceutical enterprise;
- to study the methodology for creating quality management systems in pharmaceutical enterprises;
- to acquire systemic knowledge on audit and certification issues based on the requirements of the current legislation in the field of quality;
- to teach how to apply quality management methods in the process of performing technological operations;
- to teach how to use information based on IT technologies in the field of professional activity.

10. Rationale for the choice of discipline:

Currently, the implementation of quality systems based on international GxP standards in pharmacy is becoming an urgent need. It should be noted that without ensuring a stable quality that meets the requirements of consumers, it is impossible to rationally integrate the national economy into the world economy and take a worthy place in it.

A modern pharmaceutical organization must create an effective management system that will contribute to the quality implementation of all processes, which in turn will ensure the achievement of a quality result. Thus, quality management is aimed not only at the sphere of quality management in the organization, it covers the entire management system of the company, based on a systematic approach to managing all types of activities. In this regard, the study of the discipline "Organizational Foundations of Good Practices in Pharmacy (GxP)" takes on special significance.

11. Learning outcomes (competencies)

Knowledge (cognitive sphere)	Skills and abilities (psychomotor sphere)	Personal and professional competencies (relationships)
of the main provisions of the modern concept of quality management, the mechanism	manages quality at pharmaceutical production enterprises, in pharmacy organizations, integrating quality	possesses the skills of public speaking with the presentation of their

of classical and modern methods and tools of quality management, the relationship between the concepts of Good Pharmaceutical Practices (GxP) and their role in quality assurance at all stages of the drug life cycle.	management with scientific management schools, quality management strategy into the overall strategic management system of the enterprise, applying the concept of Total Quality Management (TQM) as an effective way of business management; analyzes the quality indicators of pharmaceutical products, the relationship of product quality indicators, assessing the risks for the quality of medicines, justifying the choice of quality management methods, developing standards for operating procedures and implementing organizational and technical solutions aimed at improving quality and productivity; organizes work in entities that carry out pharmaceutical activities based on the rules of good pharmaceutical practices, managing inventory based on a process approach , creating conditions for storage, transportation and quality control of medicines and medical devices, and arguing their own choice of a method and quality management tools in accordance with legal fundamentals of quality regulation.	own judgments, analysis and synthesis of information based on partnership, trusting relationships with colleagues and healthcare workers, demonstrating multiculturalism and openness in work; engages in professional growth by demonstrating introspection skills, experience in teaching at the higher education level, searching for information in databases, organizing information and using it in writing scientific papers, to solve specific professional problems using scientific research methods, developing ideas based on critical thinking .
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12. Prerequisites: the concept of marketing research in pharmacy.

13. Postrequisites: research practice

14. Literature

Main:

1. Arystanova T.A. Pharmaceutical quality system and good pharmaceutical practices: A study guide. "Sky Systems" 2021
2. Organizational and managerial foundations of proper practices: textbook / K. D. Shertayeva, O. V. Blinova.- Zhasulan 2022
- 3.The fundamentals of the organization and management of relevant pharmaceutical practices : textbook / K. D. Shertaeva , O. V. Blinova. - Zhasulan 2022
4. Codex of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI "On the Health of the people and the healthcare system" (with amendments and additions). Chapter 2, Article 10; Chapter 5, paragraph 3; Chapter 27,28; DB "Law"<https://zan.kz> "Zan" kutyktyk akparattyk electronic database
5. Shertaeva, K. D. Organization of pharmaceutical activity : studies. the manual / K. D. Shertaeva. G. I. Utegenova.- Zhasulan 2021
6. Shertaeva, K. D. Organization of pharmaceutical activities : textbook / Shertaeva K. D. G. I. Utegenova.- Zhasulan 2021

7. Order of the Acting Minister of Health of the Republic of Kazakhstan dated February 4, 2021 No. KR DSM-15. "On the approval of good pharmaceutical practices" DB "Law" <https://zan.kz> "Zan" kutyktyk akparattyk electronic database
 8. Order of the Minister of Health of the Republic of Kazakhstan dated February 16, 2021 No. KR DSM-19 "On approval of the rules for storage and transportation of medicines and medical devices" DB "Law" <https://zan.kz> "Zan" kutyktyk akparattyk electronic database.
 9. Order of the Minister of Health of the Republic of Kazakhstan dated September 17, 2020 No. KR DSM-104/2020 On Approval of the Rules for Wholesale and Retail sale of Medicines and Medical devices. DB "Law" <https://zan.kz> "Zan" kutyktyk akparattyk electronic database
 10. Management and economics of pharmacy [Text]: textbook / edited by I. A. Narkevich. - M.: GEOTAR - Media, 2017. - 928 p.
 11. Arystanov, J. M. Management and economics of pharmacy textbook - Almaty: Evero, 2015.
- Additional:
1. Collection of legislative and regulatory legal acts regulating pharmaceutical activity in the Republic of Kazakhstan: collection / comp. B. K. Mahatov [et al.]. - Shymkent :Zhasulan, 2017. - 380 p.
 2. Collection of legislative and regulatory legal acts regulating pharmaceutical activities in the Republic of Kazakhstan: collection / composition. B. K. Makhatov [etc.]. - Shymkent: Zhasulan, 2017. - 327 pages.
 3. Arystanov, J. M. Organization of pharmaceutical activity: studies. stipend. - Almaty :Evero, 2015. - 608 p.
- Electronic resources:
1. The Educational and methodological complex of disciplines is posted on the educational portal ukma.kz
 2. Website of the Library and Information Center of the Academy lib.ukma.kz
 3. SKMA Media Library <https://media.skma.edu.kz/>
 4. Aknurpress Digital Library www.aknurpress.kz register and enter the promo code SDH-28
 5. ABOUT the Repositories <http://lib.ukma.kz/repository/>
 6. Republican Interuniversity Electronic Library
 7. Base of normative legal acts" law " <https://zan.kz/ru>
 8. Information System" paragraph Medicine " <https://online.zan.kz/Medicine/>
 10. Scopus Database <https://www.scopus.com/home.uri>
 11. Springer Database <https://link.springer.com/>

- 1. Department: Drug Technology and Pharmacology.**
- 2. The level of training: Doctoral studies.**
- 3. Educational program: Pharmacy.**
- 4. Year of study: 1**
- 5. Name of the elective discipline: Technology of dosage forms with modified release and modified action**
- 6. Number of credits: 3**
- 7. The purpose of the discipline:** The purpose of the discipline "Technology of modified medicinal species of Kazakh influence and release" is the formation and consolidation of professional skills and abilities on the issues of production of modern medicines with a highly focused therapeutic effect.
- 8. Content of discipline:** The discipline "Technology of dosage forms with modified release and modified action" is presented for the first time and is mainly due to the need for further professional development and certification of specialists at the stage of postgraduate education. With the advent of new structures and new forms of organization in the pharmaceutical industry, there is a need for personnel of various specializations. The cycle "Technology of modified-release and modified-action dosage forms" focuses on the above-mentioned key points.

9. Objectives: formation and deepening of knowledge and practical skills of doctoral students; – new dosage forms and drug delivery systems; systematization of existing knowledge and skills about drugs with targeted therapeutic effect and their application at all stages of professional pharmaceutical activity.

10. Justification of the choice of the discipline: Public health is one of the main conditions ensuring sustainable and progressive development of the state, therefore, today considerable attention is being paid to healthcare in Kazakhstan, its structure is being improved, new strategies are being introduced based on a clear vision of long-term goals, integration with all sectors of the economy, as well as on the basis of the application of modern scientific and institutional development technologies. Regulatory legal acts regulating pharmaceutical activities are issued annually. The discipline "Technology of modified-release and modified-action dosage forms" is presented for the first time and is mainly due to the need for further professional development and certification of specialists at the stage of postgraduate education. With the advent of new structures and new forms of organization in the pharmaceutical industry, there is a need for personnel of various specializations. There is an objective need for a pharmacist with comprehensive scientific knowledge about the rapidly growing arsenal of modern medicines. The cycle "Technology of modified-release and modified-action dosage forms" focuses on the above-mentioned key points.

11. Learning outcomes:

LO 1.	Demonstrates a systematic understanding of the manufacturing process of modified-release and modified-action dosage forms in good manufacturing practice.
LO 2.	Knows the principles of organizing technological processes in the production of modified-release medicines and the principles of operation of technological equipment used in the technology of modified-release medicines.
LO 3.	Uses standards and other regulatory documents when evaluating the technological process, selects and justifies the optimal equipment for the main stages of the technological process.
LO 4.	is able to use information and computer technologies in the field of professional activity; is able to transfer his own knowledge and skills in working with information (reference, scientific); presents his own judgments, analysis of scientific results in the field under study; forms out in the form of a presentation, project and presents the results of scientific research at scientific conferences, etc.
LO 5.	develops his intellectual and general cultural level; is capable of active communication in scientific, industrial and socio-public spheres of activity; is capable of self-education, introspection, self-study; is capable of perceiving information, analyzing, setting goals and choosing ways to achieve it, to generalize; has the skills of public speaking with the presentation of his own judgments, information analysis and synthesis.
LO 6.	Demonstrates a systematic understanding of the manufacturing process of modified-release and modified-action dosage forms in good manufacturing practice.

12. Prerequisites: Industrial technology of medicines, Pharmaceutical and biomedical aspects of medicines.

13. Post-requirements: Research practice.

14. Literature

Main:

1. Pharmaceutical technology. Industrial production of medicines. Vol. 1 : textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2020. 352 p. : ill. (Cipher 615.45/F 247-947861)
2. Pharmaceutical technology. Industrial production of medicines. Vol. 2 : textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2022. 448 p. : ill. (Cipher 615.45/F 247-862915)

3. Menshutina N.V., Mishina Yu.V., Alves S.V., Gordienko M.G., Guseva E.V., Troyankin A.Y. Innovative technologies and equipment for pharmaceutical production.-Vol. 2. – Moscow: BINOM Publishing House, 2016.-480 p., ill. https://vk.com/doc229684649_441671126?hash=e0fZH4p1iGlzEbAphSpmzyzcXUQDLf9I8O5jTuEcjMo
4. Order of the Ministry of Health No. KR DSM-15 dated February 4, 2021 On the Approval of Good Pharmaceutical Practices <https://adilet.zan.kz/rus/docs/V2100022167/history>
5. "Darilerdin ondiristik technolgiyasi" volume 1, Bishkek, Karaganda: "Akhnur" baspasy, 2024. 306 bet.
6. "Darilerdin ondiristik technolgiyasi" volume 2, Bishkek, Karaganda: "Akhnur" baspasy, 2024. 413 bet.

Additional information:

1. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 3: monograph / Ministry of Healthcare of the Republic of Kazakhstan. - 3rd ed. ; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. - Almaty : Publishing house "Zhibekzholy", 2014. - 872 p.
2. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 1: monograph / Ministry of Healthcare of the Republic of Kazakhstan. - 3rd ed. ; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. Almaty : Publishing house "Zhibekzholy", 2015. 720 p.
3. The State Pharmacopoeia of the Republic of Kazakhstan, vol. 2. Almaty: Zhibek Zholy Publishing House, 2009 – 804 p.
4. Pharmaceutical technology. High-molecular compounds in pharmacy and medicine: a textbook / edited by I. I. Krasnyuk. Moscow: GEOTAR - Media, 2016. 560 p.

Electronic resources:

1. Electronic resources of YUKMA JSC
2. The YUKMA Electronic Library - <https://e-lib.skma.edu.kz/genres>
3. Republican Interuniversity Electronic Library (RMEB) – <http://rmebrk.kz/>
4. Aknurpress Digital Library - <https://www.aknurpress.kz/>
5. The Epigraph Electronic Library - <http://www.elib.kz/>
6. Epigraf - multimedia textbook portal <https://mbook.kz/ru/index/>
7. EBS IPR SMART <https://www.iprbookshop.ru/auth>
8. Information and legal system "Zan" - <https://zan.kz/ru>
9. Medline Ultimate EBSSO
10. eBook Medical Collection EBSSO
11. Scopus - <https://www.scopus.com/>

1. Department: Drug Technology and Pharmacognosy.

2. Level of training: Doctoral studies.

3. Educational program: Pharmacy.

4. Year of study: 1

5. Name of the elective discipline: Pharmaceutical development and process validation.

6. Number of credits: 3

7. The purpose of the discipline: To master the skills of pharmaceutical development to create a high-quality product, including the development of composition, technology, specifications at various stages of production and the validation of manufacturing processes.

8. Content of the discipline: The pharmaceutical development process should be aimed at creating a high-quality drug and includes an informed choice of its composition, technology development, creation of a system of specifications at various stages of production, validation of analytical techniques and technological processes, technology transfer from research units to production, etc. Validation based on the life cycle of the process includes It includes product and process development, validation of an industrial-scale production process.

9. Objectives:

– creation of a high-quality drug, including an informed choice of its composition, technology development, creation of a system of specifications at various stages of production;

- justification of the choice of methods of quality control of medicines;
- development of technology for the production of finished medicines;
- Validation of technological processes.

10. Justification of the choice of the discipline: The pharmaceutical development process should be aimed at creating a high-quality drug and includes an informed choice of its composition, technology development, creation of a system of specifications at various stages of production, validation of analytical techniques and technological processes, technology transfer from research units to production, etc. Process lifecycle-based validation includes the development of a product and process, the validation of an industrial-scale production process, and the maintenance of a process in a controlled state during routine industrial production. The studied material of the discipline is presented taking into account the provisions of current legislative acts, regulatory documents, as well as requirements for conducting certain processes, registration and submission of documents.

11. Learning outcomes:

LO 1.	Demonstrates a systematic understanding of the pharmaceutical drug development and validation process in good manufacturing practice
LO 2.	He is proficient in the development and validation of various dosage forms,
LO 3.	He knows the main stages of validation of the most important operations for the production of pharmaceuticals and medical devices.
LO 4.	Possesses the skills of public speaking with the presentation of his own judgments, analysis and synthesis of information;
LO 5.	He is engaged in professional growth, demonstrates self-assessment skills.
LO 6.	Evaluates the methodology of scientific research in the field of development of pharmaceutical forms of research in accordance with national and international GMP standards.

12. Prerequisites: Industrial technology of medicines, Good pharmaceutical practice.

13. Post-requirements: Research practice.

14. Literature

Main:

1. Sagyndykova B. A., Anarbayeva R. M. Biopharmaceutical medicine zhane darilik preparattards biopharmaceuticals zertteu: oku kuraly / - Electron. text data. (2,211 KB). - Karaganda: Medet Group, 2021. – 172
2. "Darilerdin ondiristik technologiyasi" volume 2, Bishkek, Karaganda: "Akhnur" baspasy, 2024. 413 bet.
3. Pharmaceutical technology. Industrial production of medicines. Vol. 2 : textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2022. 448 p. : ill. (Cipher 615.45/F 247-862915)
4. Menshutina N.V., Mishina Yu.V., Alves S.V., Gordienko M.G., Guseva E.V., Troyankin A.Y. Innovative technologies and equipment for pharmaceutical production.-Vol.2. – Moscow: BINOM Publishing House, 2013.- 480 p., ill. https://vk.com/doc229684649_441671126?hash=e0fZH4p1iGzEbAphSpmyzzcXUQDLf918O5jTuEcjMo
5. Pharmaceutical technology. Industrial production of medicines. Vol. 1: textbook: in 2 volumes / edited by I. I. Krasnyuk [et al.]. Moscow : GEOTAR - Media, 2020. 352 p.

Additional information:

1. Order of the Ministry of Health No. kr DSM-15 dated February 4, 2021 On the Approval of Good Pharmaceutical Practices. <https://adilet.zan.kz/rus/docs/V2100022167/history>
2. Recommendation No. 19 of the Board of the Eurasian Economic Commission dated September 26, 2017 on the Guidelines for the Validation of the manufacturing process of medicinal products for Medical Use. <https://adilet.zan.kz/rus/docs/H17RK000019>
3. Pharmaceutical development: concept and practical recommendations. Scientific and practical guidance for the pharmaceutical industry / Edited by Bykovsky S.N., prof., Doctor of Chemical

Sciences Vasilenko I.A., prof., Doctor of Pharmaceutical Sciences Demina N.B., Ph.D.N. and others – M. Publishing House of Pen, 2015. – 464. <https://search.rsl.ru/ru/record/01007854838>

4. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 3: monograph / Ministry of Healthcare of the Republic of Kazakhstan. - 3rd ed. ; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. - Almaty : Publishing house "Zhibekzholy", 2014. - 872 p.
5. The State Pharmacopoeia of the Republic of Kazakhstan. Vol. 1: monograph / Ministry of Healthcare of the Republic of Kazakhstan. - 3rd ed. ; Approved by the order of the Ministry of Health of the Republic of Kazakhstan. Almaty : Publishing house "Zhibekzholy", 2015. 720 p.
6. Pharmaceutical technology. High-molecular compounds in pharmacy and medicine: a textbook / edited by I.I. Krasnyuk. Moscow: GEOTAR-Media, 2016. 560 p.
7. Ordabayeva S.K. Validation of the spectrophotometric determination of Gliderm ointment [Text] / S. K. Ordabayeva // Pharmacy of Kazakhstan. - 2006. - No. 5. - p. 28.
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