On Approval of the Rules for Conducting Pharmaceutical Inspections on Good Pharmaceutical Practices

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated January 27, 2021, No. ҚР ДСМ-9. Registered with the Ministry of Justice of the Republic of Kazakhstan on February 2, 2021, No. 22143.

Unofficial translation

In accordance with paragraph 6 of Article 244 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System", **I HEREBY ORDER:**

Footnote. The preamble is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 29.01.2025 № 6 (effective ten calendar days after the date of its first official publication).

1. To approve the Rules for Conducting Pharmaceutical Inspections on Good Pharmaceutical Practices in accordance with Annex 1 to this order.

2. To recognize as terminated some orders of the Ministry of Healthcare of the Republic of Kazakhstan according to the list in accordance with Annex 2 to this order.

3. The Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan;

3) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into effect upon the expiration of ten calendar days from the date of the first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *A. Tsoi*

Annex 1
to the Order of the

Minister of Healthcare
of the Republic of Kazakhstan
dated January 27, 2021, № ҚР ДСМ-9

Rules for conducting pharmaceutical inspections on good pharmaceutical practices

Footnote. The Rules are in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 29.01.2025 № 6 (effective ten calendar days after the date of its first official publication).

Chapter 1. General provisions

1. These Rules for conducting pharmaceutical inspections on good pharmaceutical practices and the provision of the state service "Issuance of certificates of conformity with good pharmaceutical practices" (hereinafter – the Rules) have been developed in accordance with paragraph 6 of Article 244 of the Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" (hereinafter – the Code), subparagraph 1) of Article 10 of the Law of the Republic of Kazakhstan "On state services" (hereinafter – the Law), Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 № 83 On approval of the Rules for conducting pharmaceutical inspections" (hereinafter – Decision № 83) and determine the procedure for conducting pharmaceutical inspections of good pharmaceutical practices and the procedure for providing the state service "Issuance of certificates of conformity with good pharmaceutical practices".

2. The following concepts are used in these Rules:

1) the state expert organization in the field of circulation of medicines and medical products (hereinafter referred to as the expert organization) is an entity of a state monopoly engaged in manufacture and economic activities in the field of healthcare to ensure the safety, effectiveness and quality of medicines and medical products;

2) good pharmaceutical practices in the field of circulation of medicines (hereinafter referred to as good pharmaceutical practices) – standards in the field of healthcare that apply to all stages of life cycle of medicines: good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), good distribution practice (GDP), Good Pharmacy Practice (GPP), Good Pharmacovigilance Practice (GVP) and other good pharmaceutical practices;

3) the state body in the field of circulation of medicines and medical devices (hereinafter – the state body) is a state body that carries out management in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices ;

4) the register of pharmaceutical inspectors of the Republic of Kazakhstan is an electronic information resource of the authorized body in the field of healthcare, containing information about pharmaceutical inspectors of the Republic of Kazakhstan;

5) a state service – one of the forms of implementation of individual state functions or their totality, carried out at the request or without the request of service recipients and aimed at the implementation of their rights, freedoms and legitimate interests, providing them with appropriate tangible or intangible benefits;

6) non-conformity – deviation of the object of activity from the requirements of good pharmaceutical practices, detected during inspection.

7) pharmaceutical inspector for good pharmaceutical practices – pharmaceutical inspector for appropriate pharmaceutical practices – a person authorized to perform the functions of conducting a pharmaceutical inspection for good pharmaceutical practices and included in the register of pharmaceutical inspectors of the Republic of Kazakhstan;

8) pharmaceutical inspectorate for good pharmaceutical practices (hereinafter referred to as the pharmaceutical inspectorate) – structural divisions of a state body in the field of circulation of medicines and medical devices, its territorial divisions and (or) an organization determined by the authorized body, that carry out inspections of conformity with good pharmaceutical practices for medicines and requirements for the implementation, maintenance and assessment of the quality management system of medical devices depending on the potential risk of their use;

9) pharmaceutical inspection for good pharmaceutical practices (hereinafter – the inspection) – an assessment of a facility in the field of circulation of medicines in order to determine its conformity with the requirements of good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union;

10) the e-government web portal (hereinafter – the portal) – information system, presenting one stop shop of access to all of the consolidated government information, including regulatory legal base, and to the state services, services for issuing technical conditions for connecting to networks of natural monopoly entities and services of quasi-public sector entities rendered in electronic form;

11) an electronic digital signature (hereinafter referred to as an EDS) – a set of electronic digital symbols created by means of electronic digital signature and confirming reliability of an electronic document, its belonging and invariability of its content.

3. The inspection shall be carried out for conformity of the facility of the inspected entity with the standards of good pharmaceutical practices approved by the Order of the Acting Minister of Health of the Republic of Kazakhstan dated February 4, 2021 № KR DSM-15 " On Approval of Good Pharmaceutical Practices" (registered in the Register of State Registration of Regulatory Legal Acts under № 22167) (hereinafter – Rules for pharmaceutical practices) and (or) Rules for Good Manufacturing Practice of the Eurasian Economic Union, approved by Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 № 77 and (or) Rules of Good Practice of

Pharmacovigilance of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 № 87 (hereinafter – Decision № 87).

Inspections shall be carried out:

1) for conformity with the requirements of good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), good distribution practice (GDP) of entities located on the territory of the Republic of Kazakhstan by the state body with the involvement of inspectors of the state body and/or its territorial divisions;

2) for conformity with the requirements of good pharmacy practice (GPP) by territorial divisions of the state body with the involvement of inspectors of the state body and/or its territorial divisions;

3) for conformity with the requirements of good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP) of entities located outside the territory of the Republic of Kazakhstan, as well as marketing authorization holders, and (or) other organizations engaged by the marketing authorization holder to perform pharmacovigilance obligations, located on the territory of the Republic of Kazakhstan or beyond its borders for conformity with the good practice of pharmacovigilance (GVP) by an expert organization, in coordination with the state body.

4. Inspection by an expert organization shall be carried out on the basis of an agreement concluded with the applicant in accordance with the civil legislation of the Republic of Kazakhstan.

5. Repeated inspections for confirmation of the entities who have received a certificate of conformity of the facility with the requirements of good pharmaceutical practices in the sphere of circulation of medicines, who are engaged in the manufacture of sterile medicines, as well as at which the last inspection revealed 10 (ten) or more significant non-conformities, shall be conducted during the validity period of the certificate at least once every two years in accordance with the schedule of inspections approved by the head of the state body.

Chapter 2. The procedure for conducting inspections

6. Inspections shall be carried out in a scheduled and unscheduled manner.

The basis for a scheduled inspection shall be an application of an entity in the sphere of circulation of medicines and medical devices and (or) a decision of a state body.

The basis for conducting an unscheduled inspection shall be the decision of the state body and/or the expert organization.

7. An inspection in a scheduled manner shall be carried out in cases of:

1) obtaining a certificate (opinion);

2) licensing, registration, re-registration, examination of medicines;

3) confirmation by entities that have received a certificate confirming the conformity of the facility with the requirements of good pharmaceutical practices in the field of circulation

of medicines (hereinafter referred to as the certificate), at least once every two years in accordance with the inspection schedule approved by the head of the state body in the field of circulation of medicines and medical products;

4) according to good clinical practice, is carried out before the commencement, in the course of or after completion of clinical trials of medicines, medical products of classes of potential risk of use 3, 2b and implantable medical products;

5) inspections of the pharmacovigilance system of the marketing authorization holder in cases stipulated by the rules of good pharmacovigilance practice of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

8. An unscheduled inspection shall be carried out in cases of:

1) conducting investigations related to the safety, quality and efficacy of medicines in accordance with the pharmaceutical inspection program;

2) registration, re-registration, examination of medicines;

3) according to good clinical practice is carried out in cases where, during the examination of clinical reports related to the registration of a medicine facts are identified that cast doubt on the reliability of the information provided by the applicant in the registration dossier regarding the clinical trials (tests) of medicines conducted.

9. A scheduled inspection shall be conducted by the pharmaceutical inspectorate in accordance with the inspection schedule and the pharmaceutical inspection program, in the form established by Appendix 1 to these Rules.

An inspection for conformity with the requirements of good manufacturing practices (GMP) conducted by the pharmaceutical inspectorate in accordance with the inspection schedule in accordance with the Medicines manufacturing inspection program, in the form established by Appendix1 to the Decision № 83.

10. The procedure of inspection shall consist of the following stages:

1) during a scheduled inspection - acceptance and examination of submitted documents;

during an unscheduled inspection - adoption of a decision by a government agency and/or expert organization;

2) during a scheduled inspection - agreement with the inspected entity or its authorized representative on the inspection dates;

3) formation of an inspection team;

4) preparation and sending to the inspected entity or its authorized representative of a program for conducting a pharmaceutical inspection;

5) inspection of the facility of the inspection entity, including sampling (specimens) of materials or products (if necessary) and conducting their laboratory tests;

6) drawing up a report on the inspection (hereinafter referred to as the inspection report);

7) assessment (if necessary) of the corrective and preventive action plan, a report on its implementation and evidence of the elimination of identified nonconformities;

8) making a decision on issuing or refusing to issue a certificate or report of conformity with the requirements of good pharmaceutical practices;

9) issuing a certificate.

11. In order to conduct a scheduled inspection for conformity with the requirements of good pharmaceutical practices, the inspected entity shall submit to the pharmaceutical inspectorate an application for conducting a pharmaceutical inspection of the facility in accordance with Appendices 2 and 3 to these Rules with the attachment of documents in accordance with Appendix 4 to these Rules.

12. The Pharmaceutical Inspectorate shall review the documents submitted in accordance with paragraph 11 of these Rules within 15 (fifteen) calendar days.

If there are comments on the submitted documents, the inspection entity shall eliminate the said comments within 30 (thirty) calendar days from the date of sending the comments.

13. To conduct an unscheduled inspection for conformity with the requirements of good pharmaceutical practices, the pharmaceutical inspectorate shall send the inspected entity a notification of the inspection (in any form) with the inspection deadlines.

14. An inspection team consisting of a lead pharmaceutical inspector (team leader), team members including pharmaceutical inspectors, involved experts and trainees shall be established to conduct the inspection.

The inspection team shall be formed in accordance with the procedures established by the quality system of the pharmaceutical inspectorate.

The inspection team for conformity with the requirements of Good Laboratory Practice (GLP), Good Clinical Practice (GCP) may include GMP inspectors.

15. The inspection team shall consist of two or more pharmaceutical inspectors, including a lead pharmaceutical inspector (team leader), invited experts and trainees.

Requirements for the inspection team, the qualification level of employees of the pharmaceutical inspectorate shall be established by the procedures of the pharmaceutical inspectorate quality system in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated October 13, 2020 № KR DSM-129/2020 "On approval of the rules for the formation of a pharmaceutical inspectorate, maintaining a register of pharmaceutical inspectors of the Republic of Kazakhstan" (registered in the Register of state registration of regulatory legal acts under №21435).

The duration of the inspection depends on the volume of work performed, the type and complexity of the site (section).

16. During the inspection, members of the inspection team shall not act as consultants, maintain the confidentiality of information received during the preparation and conduct of the inspection, and also maintain the confidentiality of the inspection results.

17. The lead inspector (team leader) and other members of the inspection team shall preliminarily study the documents related to the inspected activity. The lead inspector (team leader) shall ensure the preparation of the pharmaceutical inspection program. The inspection

program shall be sent to the inspected entity no later than 7 (seven) calendar days prior to the inspection start date, in case of unscheduled inspection 1 (one) calendar day in advance.

The lead inspector shall distribute functions within the inspection team and coordinates the preparatory activities related to the inspection.

18. At the beginning of the inspection, an introductory meeting shall be held with representatives of the inspected entity, at which the lead inspector introduces the members of the inspection team, gets acquainted with the management and responsible persons of the inspected entity, informs about the purpose and scope of the inspection, specifies the inspection program and schedule, makes a statement of confidentiality and answers questions from the inspected party.

The inspected entity determines the person responsible for facilitating the inspection.

19. During the inspection, changes and/or additions shall be made to the inspection program if nonconformities are identified that pose a high risk to the quality of the product, process or quality system, in agreement with the inspected entity.

20. During the inspection, the inspection team shall:

1) upon entering the facility of the inspected entity located outside the territory of the Republic of Kazakhstan, provide a document confirming the right to conduct the inspection;

2) gain access to any facility (item) within the framework of the inspection and studies it;

3) carry out audio and (or) video recording and photography, and also make copies of documents that are used as evidence when identifying non-conformities with the requirements of good pharmaceutical practices;

4) receive explanations from the inspected entity on issues arising during the inspection;

5) terminate the inspection if the inspected entity obstructs its conduct and (or) fails to provide conditions for conducting the inspection;

6) take measures or requires the inspected entity to take measures with respect to items (material evidence) that indicate non-conformity with the requirements of the rules of pharmaceutical practice, including with respect to restricting access to such items and ensuring their safety for the purpose of further investigation in the established manner.

21. The inspected entity shall ensure the possibility of performing the actions provided for by the inspection program.

22. Inspected entities located outside the territory of the Republic of Kazakhstan shall submit documentation in Kazakh or Russian and ensure the presence of a certified and (or) licensed translator with knowledge of special terminology, who shall translate from the language of the country-subject into Kazakh or Russian.

23. If necessary, during the inspection, samples (specimens) of materials or products are taken, which shall be sent by the inspected entity for testing to the testing laboratory. The costs associated with transportation, customs operations and customs control in relation to samples (specimens) of materials and products moved across the customs border, as well as testing of samples (specimens) shall be borne by the inspected entity.

24. Non-conformities shall be classified as critical, major, and minor.

1) a minor non-conformity shall be:

in the context of GMP, GDP, GPP inspections - a non-conformity that does not fall under the category of critical or significant, but is a violation of the requirements of the declared good pharmaceutical practice or a non-conformity for which there is insufficient information to classify it as major or critical;

in the context of GCP inspections - conditions, practices or processes that are not expected to have an adverse effect on the rights, safety or welfare of subjects and/or the quality and integrity of data; in GVP inspections of a pharmacovigilance system - a deficiency (non-conformity) in any component of one or more processes or procedures of a pharmacovigilance system that are not expected to have an adverse effect on the overall pharmacovigilance system or process and/or the rights, safety and welfare of patients;

2) a major non-conformity shall be:

in the context of GMP, GDP, or GPP inspections - a non-conformity with the requirements of good pharmaceutical practice that is not classified as critical but results in, or may result in, a significant deterioration in the quality of a medicine during its circulation, or a combination of non-conformities, none of which individually qualifies as major, but which collectively represent a major non-conformity;

in the context of GCP inspection - conditions, practices or processes that have an adverse effect on the rights, safety or welfare of subjects and/or on the quality and integrity of data, and include a pattern of deviations and/or numerous minor observations;

in the context of GVP inspection of the pharmacovigilance system - a major deficiency (non-conformity) in one or more processes or procedures of the pharmacovigilance system or a fundamental deficiency in any part of one or more processes or procedures of pharmacovigilance, which has a negative impact on the entire process and (or) may potentially affect the rights, safety and well-being of patients, and (or) may pose a potential danger to public health and (or) constitutes a violation of the requirements of the legislation of the Republic of Kazakhstan, which is not considered serious;

3) a critical non-conformity shall be:

in the context of GMP, GDP, GPP inspection - non-conformance with the requirements of good pharmaceutical practice, causing or resulting in a significant risk of possible reduction in the quality of the medicinal product, manufacture of the medicinal product and in the process of its circulation, dangerous to human health and life;

in the context of GCP inspection - conditions, practices or processes that adversely affect the rights, safety or well-being of subjects and/or the quality and integrity of data, as well as poor quality, manipulation and deliberate distortion of data and/or the absence of original documents;

in the context of GVP inspection of the pharmacovigilance system - a fundamental deficiency (non-conformity) of one or more processes or procedures performed in the

pharmacovigilance system, which negatively affects the entire pharmacovigilance system and (or) the rights, safety and well-being of patients and (or) represents a potential threat to public health and (or) a serious violation of the requirements of the legislation of the Republic of Kazakhstan.

25. In the event that critical non-conformities are identified, the lead inspector shall, within twenty-four (24) hours from the moment of detection, submit the relevant information to the state authority, on the basis of which the state authority shall take a decision in accordance with subparagraph 8) of paragraph 3 of the Rules for suspension, prohibition or withdrawal from circulation or restricted application of pharmaceutical products and medical products, approved by Order № ҚР ДСМ-322/2020 of the Acting Minister of Health of the Republic of Kazakhstan dated 24 December 2020 "On Approval of the Rules for suspension, prohibition or withdrawal from circulation or restricted application of pharmaceutical products and medical products" (registered in the State Register of Regulatory Legal Acts under № 21906) (hereinafter – the Rules for Suspension). The lead inspector shall also provide written notification to the inspected entity and inform law enforcement and customs authorities for the adoption of appropriate measures.

26. At the end of each day of inspection, the lead inspector shall convene a meeting with the members of the inspection team to discuss preliminary observations, which, if necessary, shall also be discussed with the responsible persons of the inspected entity. In the event of any disagreements, the members of the inspection team shall respond to the questions raised by representatives of the inspected entity. If any non-conformities are identified that are intended to be classified as critical, the lead inspector shall immediately inform the responsible persons of the inspected entity thereof.

27. At the final meeting with the responsible persons of the inspected entity, preliminary results of the inspection shall be announced with a discussion of the identified non-conformities for the subsequent preparation of a plan of corrective and preventive actions by the inspected entity (if necessary).

28. The lead inspector (team leader) shall draw up an inspection report in the form in accordance with Appendix 5 to these Rules and (or) a report on the inspection for compliance with GMP requirements in accordance with Appendix 6 to Decision № 83 and (or) a report on the results of the inspection of the pharmacovigilance system of marketing authorization holders in accordance with Appendix 6 to these Rules no later than 30 (thirty) calendar days from the date of completion of the inspection.

The inspection report shall be prepared in 2 (two) copies and signed by lead inspector (team leader) and members of the inspection team.

One copy of the inspection report shall be submitted to the inspected entity, accompanied by a cover letter, no later than five (5) calendar days from the date of its signing. The second

copy shall be retained in the archives of the state authority and/or the expert organization. In the case of an inspection for compliance with GCP requirements, the inspection report shall be submitted to the clinical trial sponsor or the marketing authorization holder.

Information provided by responsible persons of the inspected entity on the elimination of non-conformities identified during the inspection shall be accepted by the inspection team for information and is subject to indication in the inspection report as non-conformities with a note on their elimination during the inspection.

Inspection-related documents shall be retained for a period of five (5) years.

29. In cases where samples of raw materials, substances, or products are collected, the inspection report shall be prepared after the testing laboratory has provided the test results. In such cases, the period specified in paragraph 28 of these Rules shall commence from the date on which the state authority, territorial unit, or expert organization receives the test results.

30. In the event that non-conformities are identified, the inspected entity shall, no later than thirty (30) calendar days from the date of receipt of the inspection report, submit a response to the pharmaceutical inspectorate and the head of the inspection team, attaching a corrective and preventive action plan and a report on its implementation.

31. Within 15 (fifteen) calendar days from the date of receipt of the said response, the inspection team shall assess the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation.

32. The lead pharmaceutical inspector shall coordinate the assessment of the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation, with the exception of those carried out following the inspections specified in subparagraph 2) of paragraph 3 of these Rules, with the state body within 5 (five) calendar days.

33. One copy of the assessment of the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation by the state body and (or) the territorial division of the state body shall be sent to the inspected entity no later than 10 (ten) calendar days from the date of its signing, the second copy shall be kept in the archive of the pharmaceutical inspectorate and the third copy – in the expert organization (if the inspection is carried out by an expert organization).

34. The inspected entity shall be deemed to be in conformity with the requirements of the Rules for good pharmaceutical practices in one of the following cases:

in the absence of non-conformities;

subject to the rectification of the identified non-conformities.

35. Upon recognition of the inspected entity's conformity with the requirements of the Rules of Good Pharmaceutical Practices, the following documents shall be issued:

a certificate of conformity with the requirements of Good Manufacturing Practice (GMP) (except in cases where the inspection is conducted within the framework of expert evaluation

activities), Good Distribution Practice (GDP), Good Pharmacy Practice (GPP), or Good Laboratory Practice (GLP);

2) a report (opinion) shall be issued confirming conformity with the requirements of Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP);

3) a certificate of conformity with the requirements of Good Pharmacy Practice (GPP) shall be issued by the territorial subdivisions of the state authority.

To obtain a certificate of conformity with the requirements of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), the inspected entity, having received an assessment of the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation, shall submit an application in the manner prescribed by Chapter 4 of these Rules.

36. The inspected entity shall be deemed non-compliant with the requirements of Good Pharmaceutical Practice in the following cases:

1) failure to eliminate the identified non-conformities based on the results of the inspection, including the corrective and preventive action plan and the report on its implementation;

2) failure to provide a response within the deadline established by paragraph 30 of these Rules;

3) obstruction by the inspected entity of the inspection process;

4) failure by the inspected entity to ensure the conduct of the inspection as decided by the state authority.

37. The state body shall take a decision to terminate the validity of a previously issued certificate when the inspected entity refuses to undergo inspection by decision of the state body.

38. If the inspected entity is recognized as non-compliant with the requirements of good pharmacy practice, a reasoned refusal to issue a certificate for conformity with the requirements of Good Pharmacy Practice (GPP), Good Laboratory Practice (GLP) shall be issued in writing (in arbitrary form)

39. The validity period of the certificate of conformity of the facility with the requirements shall be as follows:

1) Good Manufacturing Practice (GMP) – three (3) years;

2) Good Distribution Practice (GDP) and Good Laboratory Practice (GLP) – three (3) years;

3) Good Pharmacy Practice (GPP) – for the first two times, five (5) years each; upon subsequent confirmation – permanently;

To obtain a second and permanent (upon subsequent confirmation) certificate of good pharmacy practice (GPP), the inspected entity shall submit an application to the pharmaceutical inspectorate no less than 90 (ninety) days before the expiration of the existing certificate of good pharmacy practice GPP.

40. In case of change of the name of the entity, change of the name of the location address without physical relocation of the facility, the inspected entity shall inform the state body or its territorial subdivision in writing, with the attachment of relevant documents confirming the specified information. The state body or its territorial subdivision shall reissue the certificate or opinion within 5 (five) working days.

41. The state body or its territorial division, within 5 (five) working days from the date of receipt of the application, shall issue a duplicate in the event of loss of the certificate by the inspected entity for conformance with good pharmacy practice (GPP), good laboratory practice (GLP) or the opinion on conformity with the requirements of good clinical practice (GCP), good pharmacovigilance practice (GVP).

42. The holder of the certificate of conformity with the requirements of good pharmaceutical practices shall inform the pharmaceutical inspectorate within 30 (thirty) calendar days about planned changes in the organization that affect the information specified in the application (change in the volume of products at the manufacture site, changes in premises, equipment and operations affecting the manufacture process.

Based on the nature of the changes, the pharmaceutical inspectorate shall, within 15 (fifteen) calendar days, make a decision on conducting a new inspection to verify the conformity with the requirements of good pharmaceutical practices.

43. The state body or its territorial division shall revoke the certificate or opinion in the following cases:

1) at the request of the inspected entity;

2) liquidation of the entity in the sphere of circulation of medicines and medical devices;

3) failure to eliminate the identified non-conformities based on the results of the inspection with the attachment of a plan of corrective and preventive actions and a report on its implementation based on the results of the investigation conducted on the basis of appeals of individuals and legal entities to the state body on the issue of the sale of low-quality products, non-conformity with the requirements of good pharmaceutical practices during transportation, storage and sale of medicines;

4) failure of the inspected entity to submit an application within 30 (thirty) calendar days after the completion of the cases provided for in paragraph 46 of these Rules;

5) in case of failure to eliminate the identified non-conformities based on the inspection results with the attachment of a plan of corrective and preventive actions and a report on its implementation during the inspection of manufacturers of medicines of the Republic of Kazakhstan that have a certificate of compliance with good manufacturing practice (GMP) without conducting an inspection;

6) in case of failure to eliminate the identified non-conformities based on the inspection results with the attachment of a plan of corrective and preventive actions and a report on its implementation during a repeat inspection.

44. A certificate or opinion shall cease to be valid on the basis of revocation by a government agency or its territorial subdivision, as well as upon expiration of the validity period of the certificate or conclusion.

A revoked certificate or opinion shall be subject to return to the government agency or its territorial subdivision within 5 (five) calendar days from the date of receipt by the inspected entity of the notice of revocation of the certificate.

Chapter 3. Features of conducting the inspections for conformity with the standards of good pharmaceutical practices

45. To conduct an inspection for compliance with the Good Manufacturing Practice (GMP) standard, the inspected entity shall provide a list of medicines produced at the manufacturing site (planned for production) of the manufacturer or foreign manufacturer in relation to which the inspection is carried out, in the form according to Appendix 7 to these Rules.

46. In agreement with the state inspection body, using remote interaction tools, via audio and video communication without visiting the manufacture facility of the inspected entity (hereinafter referred to as remote inspection) shall be carried out at facilities, with a corresponding note in the inspection report in the following cases:

1) the threat of occurrence, occurrence and elimination of an emergency situation and (or) the occurrence of a threat:

the spread of epidemic diseases that pose a danger to others;

diseases and injuries resulting from exposure to unfavorable chemical, biological, radiation factors;

2) occurrence of force majeure circumstances or circumstances beyond the control of the parties that pose a threat of harm to the life and health of inspectors (for example, for political , medical or other reasons).

47. To conduct a remote inspection for compliance with the requirements of good manufacturing practice, the inspected entity shall provide documents in accordance with Appendix 8 to these Rules.

48. When a manufacturer transfers part of the manufacture process and/or conducts analysis under a contract to another person (outsourcing), an additional inspection of the outsourcing organization shall be carried out, information about which is indicated in the manufacturer's application, and the manufacturer ensures a visit to the outsourcing organization.

49. Pharmaceutical inspections for conformity with the Good Laboratory Practice (GLP) standard (hereinafter - GLP inspection) are carried out in accordance with the requirements approved by the Order of the Minister of Health of the Republic of Kazakhstan dated November 4, 2020 № ҚР ДСМ-181/2020 "On approval of the rules for the assessment of materials and compliance of preclinical (non-clinical) studies with Good Laboratory Practice (

GLP) requirements of the Republic of Kazakhstan and/or the Eurasian Economic Union within the framework of pharmaceutical inspection" (registered in the Register of State Registration of Regulatory Legal Acts under №21596).

50. The procedure for conducting a GLP inspection and generating a report on the results of a preclinical trial or as part of expert work during registration, re-registration and amendments to the registration dossier shall be carried out and formalized in accordance with Appendix 1 to the Rules of Pharmaceutical Practice, as well as in accordance with the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 № 81 "On approval of the Rules of Good Laboratory Practice of the Eurasian Economic Union in the field of circulation of medicines".

51. Pharmaceutical inspections for conformity with the standard of good clinical practice (GCP) (hereinafter – GCP inspection) shall be carried out in accordance with the requirements, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated December, 11, 2020 № ҚР ДСМ-248/2020 "On approval of the Rules for conducting clinical trials of medicines and medical products, clinical and laboratory tests of medical products for diagnostics outside a living organism (in vitro) and requirements for clinical bases and provision of the state service Issuance of permit for conducting clinical trials and (or) testing of pharmacological products and medicines, medical products" (registered in the Register of regulatory legal acts under № 21772).

52. GCP inspections shall be carried out in a clinical center in sponsor's premises and (or) contractual research organization, as well as in organizations related to the study.

53. GCP inspections shall be carried out in case of identified findings during the examination of clinical trial materials, specified in Appendix 9 to these Rules.

54. When conducting GCP inspections, an inspection dossier shall be generated in the form pursuant to Appendix 10 to these Rules and a report on pharmaceutical inspection for conformity with good clinical practice in the form according to Appendix 11 to these Rules.

55. Pharmaceutical inspections for conformity with the standard of good pharmacovigilance practice (GVP) (hereinafter – GVP inspection) shall be carried out in accordance with the requirements, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated December, 23, 2020 № ҚР ДСМ-320/2020 "On approval of the Rules for conducting pharmacovigilance and monitoring of safety, quality and effectiveness of medical products" (registered in the Register of regulatory legal acts under № 21896), the standard of good pharmacovigilance practice (GVP) and (or) Decision № 87.

Chapter 4. Procedure for provision of the state service "Issuance of certificates of conformity with good pharmacological practices"

56. The state service “Issuance of certificates of conformity with the requirements of good pharmaceutical practices” (hereinafter referred to as the state service) shall be provided by a

state body (hereinafter referred to as the service provider) to individuals and legal entities (hereinafter referred to as the service recipient).

To receive the state service, the service recipient, after receiving a letter of notification on the completion of the review of the corrective and preventive action plan and a report on its implementation, submits an application in the form in accordance with Appendix 12 to these Rules through the portal of the "electronic government" www.egov.kz, www.elicense.kz (hereinafter referred to as the Portal).

The main requirements for the provision of the state service, the result of the provision and other information taking into account the specifics of the provision of the state service are provided in the List of main requirements for the provision of the state service "Issuance of certificates of conformity with good pharmaceutical practices" in accordance with Appendix 13 to these Rules (hereinafter referred to as the list of main requirements).

57. The Service Provider shall accept and register the application and documents on the day of their receipt on the portal.

When the service recipient applies after working hours, on weekends and holidays according to the Labor legislation of the Republic of Kazakhstan, the application acceptance and issuance of the result of rendering of the state service shall be carried out on the next working day.

58. Through the portal - in the “personal account” of the service recipient the status of acceptance of the application for state service and (or) a notice indicating the date and time of receipt of the result of the state service is displayed.

The service provider, within 2 (two) working days, reviews them for compliance with the list of basic requirements in accordance with Appendix 13 to these Rules, and based on the results of the review, forms one of the following results for the provision of the state service:

a certificate for conformity with the requirements of good manufacturing practice (GMP) according to Appendix 14 to these Rules;

a certificate for conformity with the requirements of good distribution practice (GDP) according to Appendix 15 to these Rules;

reasoned refusal to provide the state service in accordance with Appendix 16 to these Rules.

The result of the provision of the state service is sent through the portal - to the "personal account" of the service recipient in the form of an electronic document signed with the digital signature of the head of the service provider or his deputy.

59. The total period for the provision of the state service by the service provider is 2 (two) working days.

60. The service provider shall ensure that data on the provision of the state service is entered into the information monitoring system, for the purpose of monitoring the provision of state services in accordance with subparagraph 11) of paragraph 2 of Article 5 of the Law.

61. The authorized body sends information on the amendments and (or) additions made to the by-laws that determine the procedure for the provision of the state service to organizations that accept applications and issue the results of the provision of the state service, and to service providers (in accordance with the Register of State Services), including to the Unified Contact Center.

62. Within 3 (three) working days, the data on the inspected entities that have received the certificate shall be entered by the structural subdivision of the state body or its territorial subdivision into the Register of holders of certificate of conformity to good pharmaceutical practices (hereinafter - the Register of certificate holders) in the form according to Appendix 17 to these Rules for the period corresponding to the validity period of the certificate.

63. Information on certificates issued, suspended and revoked by the state body or its territorial subdivision shall be entered into the register of certificate holders and posted on the Internet resource of the state body or its territorial subdivision monthly by the 10th day of the month.

Chapter 5. The procedure for appealing decisions, actions (inaction) of service providers, and (or) their officials on the issues of provision of state services

64. A complaint against a decision, action (inaction) of a service provider on issues of provision of a state service shall be submitted to the name of the head of the service provider, to the authorized body for assessment and control over the quality of provision of state services.

In case of receipt of a complaint pursuant to paragraph 4 of Article 91 of the Administrative Procedural and Process-Related Code of the Republic of Kazakhstan (hereinafter – the APPRC RK), the service provider shall send it to the body considering the complaint (higher administrative body and (or) official) not later than 3 (three) working days from the date of receipt. The service provider shall not send the complaint to the body considering the complaint (superior administrative body and (or) official) in case of adoption within 3 (three) working days of a favorable act, performance of an administrative action that fully satisfies the requirements specified in the complaint.

65. The complaint of the service recipient, in accordance with paragraph 2 of Article 25 of the Law on State Services shall be reviewed:

by the service provider - within 5 (five) working days from the date of its registration;

by the authorized body for assessment and control over the quality of state services - within 15 (fifteen) working days from the date of its registration.

66. The period for consideration of the complaint by the service provider, authorized body for assessment and control over the quality of provision of state services pursuant to paragraph 4 of Article 25 of the Law on State Services shall be extended no more than 10 (ten) working days in cases of necessity:

1) conducting additional examination or verification of the complaint or on-site inspection ;

2) obtaining additional information.

In case of extension of the complaint review period, the official authorized to review complaints shall, within 3 (three) working days from the date of extension of the complaint review period, notify the service recipient who filed the complaint in writing (if the complaint is submitted on paper) or in electronic form (if the complaint is submitted electronically) of the extension of the complaint review period with indication of the reasons for the extension.

67. Unless otherwise provided by law, an appeal to the court shall be permitted after an appeal in a pre-trial manner in accordance with paragraph 5 of Article 91 of the APPRC RK.

Appendix 1
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Program for conducting a pharmaceutical inspection

1. Name of the inspected entity_____
2. Reason for conducting the inspection_____
3. Purpose of the inspection _____ ___
4. Date of the inspection _____
5. Name of the facility _____
6. Location of the facility _____
7. Composition of the inspection team and responsibility:

Item №	Surname, name, patronymic (if any) of pharmaceutical inspectors	Position, place of employment
1		

Each of the above persons visiting the facility shall be responsible for the confidentiality of information that may become known to them during the inspection.

8. Procedure of conducting the inspection_____
9. Subject-matter of the inspection _____
10. Required conditions _____

To ensure that the inspection shall be carried out properly, please:

_____

11. Procedures _____
12. Inspection schedule:

№	Date and time	Sites, divisions, systems, processes subject to inspection	Pharmaceutical inspector	Representatives of the inspected entity

Required conditions _____

To ensure that the inspection shall be carried out properly, please:

_____

11. Procedures _____

12. Inspection schedule:

№	Date and time	Sites, divisions, systems, processes subject to inspection	Pharmaceutical inspector	Representatives of the inspected entity

Appendix 2
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

For domestic applicants

To_____
(name of the state body)

Application for a pharmaceutical inspection of the facility

We ask to conduct an inspection:

_____
(indicate the purpose)
at the facility: _____
at the address: _____
In doing so. we declare:
Data of the inspected entity:
Name of the legal entity and (or) individual entrepreneur

_____
Legal address: _____
BIN/IIN _____
Address of the facility: _____

_

№ of the license for pharmaceutical activities and appendices thereto
(if any): _____

_____
Phone number, fax: _____
E-mail address: _____
Outsourcing data (if any) _____
Surname, name, patronymic (if any): _____
position of the head: _____
Head _____

(Surname, name, patronymic (if any), signature)
Authorized person of the inspected entity:

_____

(Surname, name, patronymic (if any), signature)

We hereby give our consent to the collection and processing of personal data of restricted access, constituting a legally protected secret, contained in information systems necessary for the inspection in accordance with paragraph 4 of Article 8 of the Law of the Republic of Kazakhstan "On Personal Data and Their Protection".

Appendix 3
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

For foreign applicants
To _____
(name of the expert body)

Application for a pharmaceutical inspection of the facility

We ask to conduct an inspection _____ (purpose)
at the facility: _____
At the address: _____
In doing so. we declare:
Data of the inspected entity:
Name of the legal entity and (or) individual entrepreneur:

_____

Legal address: _____
Address of the facility: _____

_

№ of the license for pharmaceutical activities and appendices thereto (if any):

_____

Phone number, fax: _____
E-mail address: _____
Outsourcing data (if any) _____
Surname, name, patronymic (if any) _____
position of the head: _____
Head: _____
(Surname, name, patronymic (if any), signature)
Authorized person of the inspected entity:

_____ _____

(Surname, name, patronymic (if any), signature)

Appendix 4
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices

List of documents, submitted by the inspected entity for conducting a pharmaceutical inspection

item №	Document name	Standard of good pharmaceutical practice					
		GMP	GDP	GLP	GCP	GVP	GPP
1	2	3	4	5	6	7	8
1.	notarized copy or an electronic copy of a valid permit (license) to carry out pharmaceutical activities or an extract from the relevant register of the country in which the inspected entity is located (for foreign applicants)) (if any)	+	-	+	-	-	-
2.	notarized copy of the document on conformity with the requirements of good pharmaceutical practice (for foreign applicants) (if any)	+	-	+	+	+	-
3.	copy of the quality guideline (concept of management a n d development of the quality	+	+	+	-		+

	system of the inspected entity)					+	
4.	copy of the organizational structure and staffing chart of the facility	+	+	+	+	+	+
5.	copy of the dossier of the manufacture site (site)	+	-	-	-	-	-
6.	list of medicines produced at the manufacture site (planned to be produced) of the manufacturer or foreign manufacturer subject to inspection	+	-	-	-	-	-
7.	list of documented standard operational procedures in electronic form (on electronic medium)	+	+	+	+	+	+
8.	list of inspections over last 5 (five) years	+	+	+	-	+	-
9.	copy of the report on the results of the last inspection (if any)	+	-	+	+	+	-
10.	master file of the pharmacovigilance system of the	-	-	-	-		-

	marketing authorization holder					+	
Documents are provided in Kazakh and/or Russian languages							

Appendix 5
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Inspection report

Name of the pharmaceutical inspectorate

_____

address, phone number, website

_____

Name of the inspected entity

_____

Address _____

Reason _____

1. Summary

Name of inspected facility	Name and full address of the facility
License	
Types of activities of the company	
Date of inspection	
Data on inspectors (experts)	Surname, name, patronymic (if any), position
Number of inspection (if any)	

2. Background information

Brief description of the inspected entity and inspected site.	
Date(s) of previous inspections	
Surname, name, patronymic (if any), position of inspectors, performed the previous inspection	
Significant changes compared to the previous inspection	
Purpose of inspection	
Inspected zones	
Personnel of the organization engaged in the inspection	
Documents provided by the inspected entity for the inspection	

3. Observations and results of the inspection.

For inspections for GMP conformity:

Quality management	
Personnel	
Premises and equipment	

Documentation	
Production	
Quality control	
Outsoursing activity	
Complaints and product recalls	
Self-inspection	
Sale and transportation of products	
Assessment of the manufacture site dossier	
Miscellaneous	

For Good Pharmacy Practice (GPP) and Good Distribution Practice (GDP) inspections - the appropriate sections of the Good Pharmacy Practice regulations are completed.

4. List of identified non-conformities

Critical	
Major	
Minor	

5. Final meeting and evaluation of the response of the inspected entity:

Comments of representatives of the inspected entity, made in the course of the final meeting	
Assessment of the inspected entity's response to identified non-conformities	
Documents and (or) samples taken during the inspection	

6. Results of inspection and recommendations:

Results of inspection	
Recommendations	

Report on pharmaceutical inspection was made and signed by:

Lead pharmaceutical inspector (Team leader)

_____ _____

(Surname, name, patronymic (if any), signature)

Members of the inspection team

_____ _____

(Surname, name, patronymic (if any), signature)

_____ _____

(Surname, name, patronymic (if any), signature)

"_____" _____ _____.

Sections 7 and 8 to be filled in by the inspection team after obtaining information on elimination of identified non-conformities and approval with the pharmaceutical inspectorate of the state body.

7. Results of consideration of elimination of identified non-conformities and findings of the inspection:

		Information on the elimination of identified	

List of identified non-conformities	Qualification of identified non-conformities	non-conformities (a summary of corrective and preventive actions, supporting document)	Assessment of the elimination of identified non-conformities

8. Conclusion

Inspected entity, name of the facility, site, address

_____

Conforms (does not conform) to the requirements of good pharmaceutical practice (specify name of good pharmaceutical practice).

Appendix 6
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Report on the results of the inspection of the pharmacovigilance system of the marketing authorization holder for medicines

_____

(name of organization-manufacturer and (or) marketing authorization holder)

_____

(name of the medicine)

1. Summary

Name, address, details of the marketing authorization holder	
Number(s) of the marketing authorization	
Summary of the activities of the marketing authorization holder	
Date(s) of conducting the inspection of pharmacovigilance system of the marketing authorization holder for medicines	
Surname, name, patronymic (if any), signature of experts (commission members), position	
Manufacture license numbers, certificates of compliance of GVP Good Pharmacovigilance Practice facilities (if applicable)	
Documents served as the grounds for the inspection	

2. Background information

Brief description of the organization-manufacturer (if applicable)	
Reason for conducting the inspection of pharmacovigilance system of the marketing authorization holder for medicines	
Personnel of the organization-manufacturer, engaged in conducting the inspection of pharmacovigilance system	

Документы, submitted by the organization-manufacturer before the inspection of pharmacovigilance system	

3. Observations and results

Responsible authorized person for pharmacovigilance, qualification (summary)	
Organizational structure of the marketing authorization holder	
Qualifty system of the marketing authorization holder	
Structure of the pharmacovigilance system of the marketing authorization holder,	
Assessment of the performance of the pharmacovigilance system for medicines	
Sources of safety data	
Computerized systems and databases	
Pharmacovigilance processes or adverse reaction monitoring processes	
Miscellaneous	

4. List of non-conformities

Critical	
Major	
Minor	

5. Conclusion

Conclusions and recommendations	

Commission members: _____ _____

Surname, name, patronymic (if any), signature

_____ _____

Surname, name, patronymic (if any), signature

_____ _____

Surname, name, patronymic (if any), signature

"_____" _____20_____

Appendix 7
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

List of medicines produced at the manufacture site (planned for production) of the manufacturer or foreign manufacturer subject to inspection

Trade name of the medicinal product or name of the	International generic name or grouping (chemical) name of		Marketing authorization, date of issuance, period of validity, or registry entry and date of	Type of product (to be specified in

pharmaceutical substance	the medicinal product or pharmaceutical substance	Dosage form, dosage (if any)	inclusion in the register for the active pharmaceutical substance (if any)	accordance with Appendix № 3)

Date of preparation "____" _____ 20____.

Head of the enterprise or authorized representative (position)

_____ _____

(Surname, name, patronymic (if any) signature)

Appendix 8
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

List of documents, submitted by the inspected entity for distant inspection for conformity with the requirements of good manufacturing practice

1. Description of the country's GMP system and regulatory framework (whether the national GMP requirements are equivalent to the GMP requirements of the Republic of Kazakhstan or the Eurasian Economic Union or to the GMP guidelines of the PIC/S Pharmaceutical Inspection Cooperation Scheme (hereinafter - PIC/S).

2. Site master file (site master file - SMF), compiled in accordance with the standard of good manufacturing practice of the Republic of Kazakhstan or GMP PIC/S manual (complete or updated 6 (six) months prior to the date of pharmaceutical inspection; information on planned changes).

3. Schematics attached to the SMF (color schematics of water treatment system, air treatment system, diagrams of piping and equipment in A3 or A2 format).

4. List of manufactured medicinal products (list of product type, trade names and international nonproprietary names, list of manufacture stages declared for inspection).

5. Total number of inspections the site has undergone, copies of GMP certificates issued during these inspections. A copy of the last inspection report with a notarized translation.

6. Photographs of the manufacture site and auxiliary systems (external general view (from the air), detailed view of rooms, indicating the processes carried out in them (sampling, weighing).

7. Qualification Master Plan (list of rooms, equipment and auxiliary systems used for manufacture and their qualification status).

8. Validation Master Plan (manufacture processes, cleaning and quality control).

9. Dossier on the product(s) series containing analytical part; list of released series for the last 3 (three) years.

10. Information on the number of claims and recalls for the previous three (3) years.

11. Information on the number of rejected series of all medicinal products.

12. List of critical, significant non-conformities, Out-of-specification (hereinafter - OOS) for the previous 3 (three) years (reports on non-conformities, OOS of the process (including reworked series) that affected the quality, safety and efficacy of medicinal products).

13. List of CAPA (corrective and preventive actions) planned and implemented after inspections for the previous 3 (three) years (including inspections of Union Member States).

14. Guarantee letter from the manufacturer's authorized person stating that the manufacture site has been fully inspected according to GMP requirements for the last 2 (two) years and the identified non-compliances have been eliminated.

15. Product quality reviews.

Appendix 9
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Comments in the expert examination of the materials of clinical trial

1) dossier quality	missing documents (e.g., no GCP declaration, no audit certificates, no information on the monitoring process);
	data inconsistency;
	problems with the quality of the dossier in the past for this applicant;
2) medicine type (recombinant drug, cell therapy, gene therapy, active substance that is a new chemical compound, blood product, orphan drug, other);	
3) applicant and/or sponsor and/or contract research organization (to which the main and/or relevant parts of the conduct of the trial have been delegated):	first application from a new applicant;
	previous inspection experience (never inspected and/or long time since last inspection and/or inspection with negative result);
4) target population (children, other vulnerable, critically ill patients, emergency conditions, all types);	
5) information from third country authorities about negative inspection outcome (e.g. US FDA, EMA, others);	
6) location of the country where the clinical trial was conducted, outside the territories of ICH countries;	
7) ethics	No indication of ethics committee review of all or some clinical trial documents (e.g., protocol, subject and informed consent information, recruitment procedures) and research centers;
	no description of the ethical aspects of the study (e.g., inclusion of vulnerable patients, high incidence of illiteracy in the study population, witness requirement) and problems encountered (if any);
	failure of the informed consent process or information provided by the research centers; no description of the ethical aspects of the study (e.g., inclusion of vulnerable patients, high incidence of illiteracy in the study population, witness requirement) and problems encountered (if any); failure of the informed consent process or information provided by the research centers

8) researchers and the administrative structure of the study: complex administrative structure (e.g., involvement of a large number of contract research organizations and/or vendors, subcontractors);	
9) Study plan	study design factors (e.g., complexity of study design, insufficient justification for the use of placebo and/or choice of active comparator);
	major protocol changes during the study (e.g., changes in primary endpoints or statistical methods or inclusion and/or non-inclusion criteria) and/or a large number of protocol amendments
	Intervention factors: the authenticity and characteristics of the studied medicine and interventions are unclear: 1) inconsistencies between the protocol and study report regarding dosage forms, packaging, labeling, storage conditions, dose, dosing regimen, and duration of dosing; 2) particular susceptibility to instability of the study drug product under improper storage or transportation conditions; 3) preparation by pharmaceutical and/or clinical staff prior to administration; 4) modification of the study drug during the study; 5) complex dose titration or escalation;
10) criteria and data for assessing efficacy and safety	unclear or unexplained differences in the definition of study variables between the protocol and the clinical trial report;
	changes in facilities where critical measurements are made;
	assessment of clinical outcomes: if someone other than the investigator was responsible for assessing clinical outcomes (e.g., sponsor, external assessors, or external committee), the following elements of the data flow process should be considered: appropriate instructions and/or training for researchers to collect and report performance parameters; identification and independence of external assessors and/or committee; procedures for preparing, reviewing, evaluating, and documenting outcomes, including how blinding is maintained;
11) statistical methods	changes in statistical methods and/or endpoints at the time of and/or after the study, in particular changes made prior to unblinding and/or unplanned statistical analysis;
	patient(s) data excluded from analysis without justification or on grounds of concern, in particular if the results favor the test drug or if the decision(s) to exclude data are made after unblinding of the data;
	results contradict known literature data or other study results;
	data with an unusual trend or abnormal magnitude of variation or extremely small deviations (high or low variability in efficacy parameters that have high or low

	natural variability; unexpectedly low rates of reports of (serious) adverse events or concomitant medications);
12) implausibility and/or inconsistency of the clinical data provided:	Inconsistent, incorrect or incomplete data recording and reporting: incorrect design of the individualized registration record (hereinafter referred to as IRR) (e.g. protocol amendments are not reflected in the IRR); lack of relevant data lists; inconsistency between patient data lists and reported data in the clinical trial report; large number of missing values.

Appendix 10
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Format of the Inspection Dossier

1. Contents.
2. Contacts:
1) With the requesting party;
2) with the lead inspector(s)
and the involved inspectors;
3) With the evaluators;
4) With the applicant and/or sponsor;
5) With the inspected persons.
3. Documents related to the study (if any).
Provided by the applicant and/or sponsor:
1) protocol and amendments;
2) clinical trial report;
3) investigator's brochure;
4) blank patient informed consent forms;
5) patient list and audit trails.
Provided by the expert (evaluator):
1) clinical trial report (if applicable);
2) expert reports;
3) list of questions;
4) response to the request.
4. Documents related to the inspection:
1) inspection request;
2) composition of the inspection team (central and for each selected center);
3) contracts;

4) planning documents for the study.

5. Locally collected information of general importance:

Documents seized or copied during the inspection.

6. Inspection reports:

Inspection reports (including the responses of the inspected person(s) and evaluation of the summary inspection report (final version).

Appendix 11
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Report on conducting a pharmaceutical inspection for conformity with good clinical practice

Name of the pharmaceutical inspectorate

_____

address, phone number, website _____

___

Name of the inspected entity _____

Address _____

Reason _____

1. Summary

Name of inspected facility (underline as necessary): Contract Research Organization Sponsor Clinical Site(s)	Name and full address of the facility
License	
Types of activities of the company	
Date of inspection	
Data on inspectors (experts)	Surname, name, patronymic (if any), position
Number of inspection (if any)	
Full name of the clinical trial	
Protocol identification code version (number) and date (any amendment to the protocol has a version number and date)	
Application number	
Number in international clinical trial databases	
Trial duration	
Information about the Sponsor: Name and address of the organization, surname, name, patronymic (if any) of the contact person	
Information about the Applicant:	

Sponsor Official representative of the Sponsor A person or organization authorized by the sponsor to submit this application (in this case, indicate the last name, first name, patronymic (if any) of the contact person, address, contact information (phone number, fax, e-mail)	
Clinical site	Name and address
For bioequivalence studies	Name and address of the bioanalytical part of the clinical trial
Details of inspection	
Date of inspection	
Type of inspection:	

2. Background information

Brief description of the inspected entity and inspected site.

Date(s) of previous inspections

Surname, name, patronymic (if any), position of inspectors,
conducted the previous inspection

Significant changes compared to the previous inspection

Purpose of inspection

Inspected zones

Personnel of the organization engaged in the inspection

Documents provided by the inspected entity for the inspection

3. Observations and results of the inspection.

For inspections for GCP conformity:

Quality management	
Personnel	
Premises and equipment	
Documentation	
Archives	
Outsoursing activity	
Self-inspection	
Reports of adverse reactions or events	
Evaluation of the clinical trial master file	
Management of the investigational medicinal product	
Miscellaneous	

4. Final meeting and evaluation of the response of the inspected entity:

Comments from representatives of the inspection subject made during the final meeting

Evaluation of the response of the inspection subject to the identified non-conformities

Documents and (or) samples taken during the inspection

5. Inspection results and recommendations:

Inspection results

Recommendations

The report on the pharmaceutical inspection was prepared and signed by:

Lead pharmaceutical inspector (Team leader)

_____ _____

(Surname, name, patronymic (if any) signature)

Members of the inspection team

_____ _____

(Surname, name, patronymic (if any) signature)

_____ _____

(Surname, name, patronymic (if any) signature)

"_____" _____ _____.

Sections 6 and 7 are completed by the inspection team after receiving information on eliminating the identified non-conformities and agreement with the pharmaceutical inspectorate of the state body.

6. Results of the review of the elimination of identified non-conformities and the conclusions of the inspection:

List of identified non-conformities	Qualification of identified non-conformities	Information on the elimination of identified non-conformities (a summary of corrective and preventive actions, supporting document)	Assessment of the elimination of identified non-conformities

7. Conclusion

Inspected entity, name of the facility, site, address

_____

Conforms (does not conform) to the requirements of good pharmaceutical practice (specify name of good pharmaceutical practice).

Appendix 12
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Application for issuance a certificate on conformity with good pharmaceutical practices

To _____

(name of the state body)

Please issue a certificate of conformity to the requirements of Good Manufacturing Practices (GMP) or Good Distribution Practices (GDP)

for the facility: _____

(full name of the facility)

located at the address: _____

(address of the facility)
Data of the inspected entity:
Name of the legal entity and (or) individual entrepreneur

_____

Legal address: _____
BIN/IIN _____
№ of the license for pharmaceutical activities and appendices thereto
(if any):

_____

Phone number, fax, e-mail: _____
E-mail address: _____
Information about the applicant _____

___

(developer, manufacturer (producer), distributor, authorized person)
Address of location (phone number, fax, e-mail) _____
Date and number of the power of attorney (a copy of the power of attorney) _____

_____

(When registering an application through the portal, the electronic version)
Period of the inspection _____
For production: _____
(type of products)
Dosage form

_____

Head _____ _____
(Surname, name, patronymic (if any), signature)

We give our consent to the collection and processing of restricted access data, constituting a secret protected by law, contained in the information systems necessary for the inspection in accordance with paragraph 4 of Article 8 of the Law of the Republic of Kazakhstan “On personal data and their protection”.

Appendix 13
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

List of main requirements to provision of the state service
"Issuance a certificates on conformity with good pharmaceutical practices"

Name of the state service “Issuance of certificates for conformity to Good Pharmaceutical Practices” Name of the subspecies of the state service: 1) issuance of certificate for conformity to the requirements of good manufacturing practices GMP); 2) issuance of a certificate of conformity to the requirements of Good Distribution Practice (GDP).

1.	Name of the service provider	Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan
2.	Methods of providing the state service	For all subtypes: Web portal of " e-government": www.egov.kz, www.elicense.kz (hereinafter - portal)
3.	Term of providing the state service	For all subtypes: Issuance of a certificate - two (2) working days;
4.	Form of providing the state service	For all subtypes: electronic (partially automated)/ paper
5.	Result of providing the state service	1) issuance of a certificate of conformity to the requirements of Good Manufacturing Practice (GMP); 2) issuance of certificate of conformity to the requirements of Good Distribution Practice (GDP); 3) motivated refusal to provide a state service according to Annex 16 to these Rules.
6.	The amount of the fee charged from the service recipient when providing the state service and methods of its collection in cases provided for by the legislation of the Republic of Kazakhstan	The state service is provided free of charge
7.	Work schedule of the service provider and information objects	1) service provider - from Monday to Friday, in accordance with the established work schedule from 9.00 to 18.30 hours, except for weekends and holidays, according to the Labor Code of the Republic of Kazakhstan with a lunch break from 13.00 to 14.30 hours. 2) portal - round the clock, except for technical breaks due to repair works (when the service recipient applies after working hours, on weekends and holidays, according to the Labor Code of the Republic of Kazakhstan, acceptance of applications and issuance of the result of state service is carried out on the next working day).
		To obtain a certificate of conformity to the requirements of Good Manufacturing Practice (GMP) and (or) certificate of conformity to the

8.	List of documents and information required from the service recipient for provision of the state service	requirements of Good Distribution Practice (GDP) - application in the form according to Annex 12 to these Rules.
9.	Grounds for refusal in provision of the state service, established by the laws of the Republic of Kazakhstan	1) establishment of unreliability of the documents submitted by the service recipient to receive a state service and (or) data (information) contained in them; 2) non-compliance of the service recipient and (or) submitted materials, data and information necessary for provision of state service with the requirements of these Rules.
10.	Other requirements subject to the provision of the state service	The service recipient has the opportunity to receive information on the procedure and status of state service provision in the remote access mode through the portal - in the “personal cabinet”, as well as a single contact center. Contact phone numbers of reference services on issues of state service provision are indicated on the Internet resource of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan kmfk@dsm.gov.kz. Telephone numbers of the single contact center on issues of state service provision are 1414, 8-800-080-7777.

Appendix 14
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Eurasian Economic Union

_____

(name of the authorized body)

Certificate

of GMP Compliance of a Manufacturer in Accordance with the Good Manufacturing Practice Requirements of the Eurasian Economic Union

№ GMP/EAEU/KZ/000XX-20XX

(certificate reference number)

Validity period is from_____to _____

Issued following a pharmaceutical inspection in accordance with the Rules for conducting pharmaceutical inspections on good pharmaceutical

practices, approved by the Decision

of the Council of the Eurasian Economic Commission dated November 3, 2016 № 83

_____

(full and abbreviated names of the authorized body)

_____

hereby confirms the following:

a pharmaceutical inspection of

_____

(full name of the manufacturer)

has been conducted

_____

(manufacturing site address)

on the basis of (indicate one of the following):

application № for obtaining a permit (license) to carry out activities for the manufacture of medicines;

plan of pharmaceutical inspections, as a holder of a permit (license) for the manufacture of medicines № _____;

application № _____ for registration of medicines;

_____

(other grounds)

Based on the information obtained during inspections, the most recent of which was conducted on _____ (date,

period), it has been established that this pharmaceutical manufacture complies with the requirements of the Good Manufacturing Practice Rules of the Eurasian Economic Union, which are equivalent to the Principles and Guidelines of Good Manufacturing Practice of the European Union for medicinal products for human and veterinary use, as well as the principles of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than 3 years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all sheets (both main and supplementary sheets).

The authenticity ((originality) of this certificate may be verified in the database of

_____.

(name of the authorized body)

If it does not appear in the indicated database, please contact the issuing authority.

_____ (form reference number)

(supplementary sheet)

Medicinal products for human use	
Medicinal products for clinical trials (tests)	
Code	Name
1. Manufacturing operations – medicinal products	
1.1	Sterile products
	1.1.1 Aseptically prepared (processing operations for the following dosage forms):
	1.1.1.1. Large volume liquids
	1.1.1.2. Small volume liquids
	1.1.1.3. Lyophilisates
	1.1.1.4. Solids and implants
	1.1.1.5.Semi-solids
	1.1.1.6. Other products, aseptically prepared _____ _____ (specify)
	1.1.2. Terminally sterilised (processing operations for the following dosage forms):
	1.1.2.1. Large volume liquids
	1.1.2.2. Small volume liquids
	1.1.2.3. Solids and implants
	1.1.2.4. Semi-solids
	1.1.2.5. Other products, terminally sterilised _____ _____ (specify)
	1.1.3. Batch certification (batch release)
1.2	Non-sterile products
	1.2.1. Non-sterile products (technological operations for the following dosage forms):
	1.2.1.1. Capsules, hard shell
	1.2.1.2. Capsules, soft shell
	1.2.1.3. Chewing dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for external use
	1.2.1.6. Liquid dosage forms for internal use
	1.2.1.7. Medicinal gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressured preparations
	1.2.1.10. Radionuclide generators
	1.2.1.11. Semi-solids
	1.2.1.12. Suppositories (Suppositories)
	1.2.1.13. Tablets

	1.2.1.14. Transdermal patches
	1.2.1.15. Other non-sterile products _____ (specify)
	1.2.2. Batch certification (certification of the series)
1.3	Biological medicinal products
	1.3.1. Biological medicinal products:
	1.3.1.1. Blood products
	1.3.1.2. Immunological products
	1.3.1.3. Somatic cell-based products (somatic cell therapy products)
	1.3.1.4. Gene therapy products
	1.3.1.5. Biotechnology products
	1.3.1.6. Products, extracted from animal or human organs (tissues)
	1.3.1.7. Tissue engineering products (products of tissue engineering)
	1.3.1.8. Other biological medicinal products _____ _____(specify)
	1.3.2. Batch certification (certification of the series) (list of product types):
	1.3.2.1. Blood products
	1.3.2.2. Immunological products
	1.3.2.3. Somatic cell-based products (somatic cell therapy products)
	1.3.2.4. Gene therapy products
	1.3.2.5. Biotechnology products
	1.3.2.6 Products, extracted from animal or human organs (tissues)
	1.3.2.7. Tissue engineering products (products of tissue engineering)
	1.3.2.8. Other biological medicinal products _____ _____ (specify)
1.4	Other medicinal products or processing activity
	1.4.1. Production:
	1.4.1.1. Herbal products
	1.4.1.2. Homoeopathic products
	1.4.1.3. Other products _____ (specify)
	1.4.2. Sterilisation of pharmaceutical substances, excipients, finished products:
	1.4.2.1. Filtration
	1.4.2.2. Dry heat sterilisation
	1.4.2.3. Moist heat sterilisation
	1.4.2.4. Chemical sterilisation
	1.4.2.5. Gamma irradiation sterilisation

	1.4.2.6. Electron beam sterilisation
	1.4.3. Other _____ (specify)
1.5	Packaging
	1.5.1. Primary packing:
	1.5.1.1. Capsules, hard shell
	1.5.1.2. Capsules, soft shell
	1.5.1.3. Chewing dosage forms
	1.5.1.4. Impregnated dosage forms
	1.5.1.5. Liquid dosage forms for external use
	1.5.1.6. Liquid dosage forms for internal use
	1.5.1.7. Medicinal gases
	1.5.1.8. Other solid dosage forms
	1.5.1.9. Pressurized preparations
	1.5.1.10. Radionuclide generators
	1.5.1.11. Semi-solids
	1.5.1.12. Suppositories (suppositories)
	1.5.1.13. Tablets
	1.5.1.14. Transdermal patches
	1.5.1.15. Other non-sterile medicinal products _____ _____(specify)
	1.5.2. Secondary packing
1.6	Quality control
	1.6.1. Microbiological testing: sterility
	1.6.2. Microbiological testing: microbiological purity
	1.6.3. Chemical(physical) testing
	1.6.4. Biological testing
With respect to any restrictions or clarifications related to the manufacturing operations (except where such clarification constitutes a general comment regarding the processes at the manufacturing site), wherever such restrictions or clarifications apply, a reference to the corresponding item number of the GMP certificate must be included.	
2. Importation of medicinal products	
2.1	Quality control of imported medicinal products
	2.1.1. Microbiological testing: sterility
	2.1.2. Microbiological testing: microbiological purity
	2.1.3. Chemical(physical) testing
	2.1.4. Biological testing
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile products:
	2.2.1.1. Aseptically prepared
	2.2.1.2. Terminally sterilised
	2.2.2. Non-sterile products
	2.2.3. Biological medicinal products:

	2.2.3.1. Blood products
	2.2.3.2. Immunological products
	2.2.3.3. Somatic cell therapy products (products for somatic cell therapy)
	2.2.3.4. Gene therapy products
	2.2.3.5. Biotechnology products
	2.2.3.6. Products, extracted from animal or human organs (tissues
	2.2.3.7. Tissue engineering products (products of tissue engineering)
	2.2.3.8. Other biological medicinal products _____ _____ (specify)
2.3	Other importation activity (import)
	2.3.1. Site of physical importation (import)
	2.3.2. Importation of intermediate products which undergoes further processing
	2.3.3. Other_____ (specify)
3. Manufacturing operations – pharmaceutical substances	
Pharmaceutical substance (substances):	
3.1	Manufacture of pharmaceutical substances by chemical synthesis
	3.1.1. Manufacture of pharmaceutical substance intermediates
	3.1.2. Manufacture of crude pharmaceutical substance
	3.1.3. Salt formation (Purification): specify (e.g. recrystallization)
	3.1.4. Other _____ (specify)
3.2	Manufacture of pharmaceutical substances by methods of extraction from natural sources
	3.2.1. Extraction of pharmaceutical substance from plant source
	3.2.2. Extraction of pharmaceutical substance from animal source
	3.2.3. Extraction of pharmaceutical substance from human organ (tissue) source
	3.2.4. Extraction of pharmaceutical substance from mineral source
	3.2.5. Modification of extracted pharmaceutical substance (specify source from items 3.2.1 – 3.2.4)
	3.2.6. Purification of extracted pharmaceutical substance (specify source from items 3.2.1 – 3.2.4)
	3.2.7. Other_____ (specify)
3.3	Manufacture of pharmaceutical substance using biological processes
	3.3.1. Fermentation

	3.3.2. Manufacture using cell cultures _____ _ (specify the type of cells used) (The indication of the cell type refers to their specific characteristics, including but not limited to cell lineage, strain, and other relevant specifications.)
	3.3.3. Extraction (purification)
	3.3.4. Modification
	3.3.5. Other_____ (specify)
3.4	Manufacture of sterile pharmaceutical substances (sections 3.1, 3.2, 3.3 must be filled in, where applicable)
	3.4.1. Pharmaceutical substances, aseptically prepared
	3.4.2. Pharmaceutical substances, terminally sterilised
3.5	Final stages of the manufacture of pharmaceutical substances
	3.5.1. Stages of physical processing _____ ___ (specify, e.g. drying, milling, sieving))
	3.5.2. Primary packing
	3.5.3. Secondary packing
	3.5.4. Other _____ (specify for operations
	not described above)
3.6	Quality control
	3.6.1. Physical (chemical) testing
	3.6.2. Microbiological testing (including sterility testing)
	3.6.3. Microbiological testing (excluding sterility testing)
	3.6.4. Biological testing
4. Other operations – pharmaceutical substances	
_____ _____	
(specify)	
Any restrictions or clarifying remarks,	
related to the scope of this certificate:	
_____	
_____	
_____ _____	
(Surname, name, patronymic (if any), position) (signature)	
_____	
(date of signing, dd.mm.yyyy)	
Seal	
_____	

(form reference number)

Any comments enclosed in parentheses within the text of the certificate are not part of the official certificate content and are provided for informational purposes only.

Appendix 15
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Ministry of Health of the Republic of Kazakhstan Committee of Medical and Pharmaceutical Control Certificate of Compliance with Good Pharmaceutical Practices in the Field of Medicinal Product Circulation

№ _____
Date of issue "____" _____ ____
Valid until "____" _____ ____
Issued by _____
(full name, location of the facility)

_____
(name of the facility)
On the basis of information received in the course of pharmaceutical inspection,
the latter of which was conducted on "____" _____ 20____
and confirms the compliance with

_____
(standard of good pharmaceutical practice)
State body issued the certificate

_____
(полное name)
Head of the state body

_____ _____
Surname, name, patronymic (if any) signature

* The validity period of the certificate is indicated from the date of the last day of the last pharmaceutical inspection of the subject in the field of
circulation of medicinal products.

Appendix 16
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

[Name of the service provider]		[Name of the service provider]

Reasoned refusal to provide a state service

Date of issue: [date of issue]
[Name of the service recipient]
Place of registration: Region:
[Region] District: [District]
City/locality: [City/locality]
[Business Identification Number] [BIN]
Date of state registration dated [Date]
Reason of refusal: [Reason of refusal] [Position of the signatory]
[Surname, name, patronymic (if any) of the signatory]
[Position of the signatory] [Surname, name, patronymic (if any)]

Appendix 17
to the Rules for conducting
pharmaceutical inspections on good
pharmaceutical practices
Form

Register of the holders of the certificate for compliance with good pharmaceutical practices

Item №	Name, legal address, phone number of the certificate holder	Address of the facility of the certificate holder	Number of certificate, date of issue, validity period	Scope of compliance with standards	Information regarding the suspension or withdrawal of the certificate
1	2	3	4	5	6

Annex 2
to the order of the
Minister of Healthcare
of the Republic of Kazakhstan
dated January 27, 2021, № ҚР ДСМ-9

List of terminated orders of the Ministry of Healthcare of the Republic of Kazakhstan

1. Order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 742 "On Approval of the Rules for Conducting Pharmaceutical Inspections on Good Pharmaceutical Practices" (registered in the Register of State Registration of Regulatory Legal Acts under № 5942, published in 2010 in the Collection of Acts of Central Executive and Other central state bodies of the Republic of Kazakhstan № 7).

2. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated November 6, 2014 № 223 "On Amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 742 "On Approval of the Rules for Inspection in the Sphere of Circulation of Medicines, Medical Devices and

medical equipment" (registered in the Register of State Registration of Normative Legal Acts under № 9864, published on November 17, 2014, in the information and legal system "Adilet ").

3. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 27, 2015 № 396 "On amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 742 "On approval of the Rules for conducting inspections in the field of circulation of medicines, medical devices and medical equipment" (registered in the Register of State Registration of Normative Legal Acts under № 11496, published on July 14, 2015, in the information and legal system "Adilet ").

4. Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 10, 2019 , № KR DSM-26 "On amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 742 "On approval of the Rules for conducting inspections in the field of circulation of medicines, medical devices and medical equipment" (registered in the Register of State Registration of Regulatory Legal Acts under № 18511, published on April 23, 2019, in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

5. Order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 743 "On approval of the Rules for assessing production conditions and a quality assurance system during state registration of a medicinal product or medical device" (registered in the Register of State Registration of Normative Legal Acts under № 5933, published in the 2010 year in the Collection of acts of the central executive and other central state bodies of the Republic of Kazakhstan № 5).

6. Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 16, 2019 , № KR DSM-40 "On Amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 № 743 "On Approval of the Rules for Assessing Production Conditions and the Quality Assurance System during State Registration of Medicinal Products, medical devices and medical equipment" (registered in the Register of State Registration of Regulatory Legal Acts under № 18547, published on April 26, 2019, in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

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