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 subparagraph 44) of Article 7 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system", **I ORDER**:

Footnote. The preamble is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 17.01.2023 № 8 (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 appropriate pharmaceutical practices

Footnote. The rules are in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 17.01.2023 № 8 (effective ten calendar days after the date of its first official publication).

Chapter 1. General provisions

1. These Rules for conducting pharmaceutical inspections on appropriate pharmaceutical practices and the provision of public services "Issuance of certificates of compliance with appropriate 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 the Health of the People and the Healthcare System" (hereinafter – the Code), subparagraph 1) of Article 10 of the Law of the Republic of Kazakhstan "On Public services" (hereinafter – The Law) and determine the procedure for conducting pharmaceutical inspections of appropriate pharmaceutical practices and the procedure for providing the state service " Issuance of certificates of compliance with appropriate 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 a subject of a state monopoly engaged in production 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 drug circulation (hereinafter referred to as good pharmaceutical practices) – health standards that apply to all stages of the 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) public service is one of the forms of realization of certain state functions carried out individually on the request or without the request of service recipients and aimed at the

realization of their rights, freedoms and legitimate interests, providing them with appropriate tangible or intangible benefits;

6) nonconformity – deviation of the object of activity to the requirements of good pharmaceutical practices, identified during the inspection.

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

8) pharmaceutical inspectorate for appropriate 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 an authorized body that carries out inspections of compliance with appropriate pharmaceutical practices for medicines and requirements for the implementation, maintenance and evaluation of the system quality management of medical devices, depending on the potential risk of their use;

9) pharmaceutical inspection for appropriate pharmaceutical practices (hereinafter referred to as inspection) – an assessment of an object in the field of circulation of medicines in order to determine its compliance with the requirements of appropriate pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union;

10) the e-government web portal (hereinafter referred to as the portal) is an information system that represents a single window of access to all consolidated government information, including the regulatory framework, and to public services, services for issuing technical specifications for connection to the networks of natural monopoly entities and services of quasi–public sector entities provided in electronic form the form;

11) an electronic digital signature (hereinafter referred to as an EDS) is a set of electronic digital symbols created by means of an electronic digital signature and confirming the authenticity of an electronic document, its belonging and the immutability of its content.

3. The inspection is carried out for compliance of the object of the subject of inspection 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 of Pharmaceutical Practices) and Rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by Decision № 77 of the Council of the Eurasian Economic Commission of November 3, 2016, Rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union, approved by Decision № 87 of the Council of the Eurasian Economic Commission of November 3, 2016 (as amended by Decision № 81 of the EEC Council of May 19 2022).

Inspections are carried out:

1) for compliance 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 a state body with the involvement of inspectors of its territorial divisions;

2) for compliance with the requirements of good pharmacy practice (GPP) by territorial divisions of the state body;

3) for compliance 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 holders of registration certificates for compliance with good pharmacovigilance practice (GVP), and (or) other organizations engaged by the holder of the registration certificate to perform pharmacovigilance obligations, located on the territory of the Republic of Kazakhstan or beyond its borders for compliance with the good practice of pharmacovigilance (GVP) by an expert organization, in coordination with the state body.

4. The costs of organizing and conducting inspections by an expert organization shall be borne by the applicant on the basis of an agreement concluded with an expert organization in accordance with the civil legislation of the Republic of Kazakhstan.

5. In agreement with the state body, inspections using means of remote interaction, by means of audio and video communication without visiting the production facility of the subject of inspection (hereinafter referred to as remote inspection) are carried out at facilities with an appropriate mark in the inspection report in the following cases:

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

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

diseases and lesions resulting from exposure to adverse chemical, biological, and radiation factors;

2) the 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).

6. If the result of the remote inspection is positive, after the completion of the cases provided for in paragraph 5 of these Rules, an inspection is carried out with a visit to the inspection subject on the basis of the application of the inspection subject (hereinafter referred to as the application) in accordance with Annexes 1 and 2 to these Rules.

If the inspection subject fails to submit an application within 30 (thirty) calendar days after the completion of the cases provided for in paragraph 5 of these Rules, the certificate issued as a result of remote inspection is withdrawn or measures are taken in accordance with the requirements approved by Order of the Acting Minister of Health of the Republic of Kazakhstan dated December 24, 2020 № KR DSM-322/2020 "On approval of the suspension rules, prohibition or withdrawal from circulation or restriction of the use of medicines and

medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 21906) (hereinafter – the Rules of Suspension).

7. An inspection group consisting of a leading pharmaceutical inspector (team leader), group members, including pharmaceutical inspectors, experts and interns involved, shall be established to conduct the inspection.

8. The inspection team consists of two or more pharmaceutical inspectors, including the lead pharmaceutical inspector (team leader).

The requirements for the inspection group, the level of qualification of the staff of the pharmaceutical inspectorate and the experts involved in the work of the inspection group are established by the procedures of the quality system of the pharmaceutical inspectorate 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 the pharmaceutical Inspectorate, maintaining the Register of Pharmaceutical Inspectors of the Republic of Kazakhstan" (registered in The Register of State Registration of normative legal Acts under № 21435).

9. During the inspection, pharmaceutical inspectors do not act as consultants, respect the confidentiality of information obtained during the preparation and conduct of the inspection, and also maintain the confidentiality of the inspection results.

Chapter 2. The procedure for conducting inspections

10. The inspection is carried out in the cases provided for in paragraph 3 of Article 244 of the Code.

11. In order to carry out an inspection for compliance with the requirements of good pharmaceutical practices, the subject of inspection submits an application to the pharmaceutical inspectorate in accordance with Annexes 1 and 2 to these Rules.

The inspection subject shall attach documents to the application in accordance with Annex 3 to these Rules.

After receiving the notification, the applicant or the holder of the registration certificate submits an application to the expert organization for a pharmaceutical inspection through the "personal account" through the information system of the expert organization.

12. The Pharmaceutical Inspectorate shall consider 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 subject of the inspection shall eliminate these comments within 30 (thirty) calendar days from the date of sending the comments.

13. In order to carry out inspections for compliance with the requirements of good laboratory practice (GLP) and good clinical practice (GCP), the pharmaceutical inspectorate sends the applicant a notice of inspection (in any form).

14. In order to carry out an inspection during the examination of medicines, the expert organization sends the applicant a notification of the inspection.

The duration of the organization and conduct of the inspection does not exceed 120 calendar days from the date of submission by the applicant or the holder of the registration certificate of the application for a pharmaceutical inspection. The deadlines for notifying the subjects of the pharmaceutical inspection of the pharmaceutical inspection are not included in the duration of the organization and conduct of the inspection.

15. Repeated inspections are carried out to confirm by subjects who have received a certificate of compliance of the facility with the requirements of good pharmaceutical practice in the field of circulation of medicines, production of sterile medicines, as well as those who revealed 10 (ten) or more significant inconsistencies during the last inspection. It is carried out 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.

16. The Pharmaceutical Inspection includes the application in the inspection schedule and sends the inspection team electronic copies of the documents specified in paragraph 11 of these Rules. The Lead pharmaceutical inspector (head of the group) ensures the preparation of the pharmaceutical inspection program (hereinafter referred to as the inspection program) in accordance with Annex 4 to these Rules. The inspection program is signed by the inspection team and sent to the inspection facility 7 (seven) calendar days before the start of the inspection at the facility.

17. The Lead Pharmaceutical inspector (head of the group) distributes functions in the inspection group and coordinates preparatory activities.

18. The inspection team preliminarily examines the documents submitted by the subject of the audit related to the activity being audited.

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

20. At the beginning of the inspection, an introductory meeting is held with representatives of the inspected entity, at which the lead pharmaceutical inspector (team leader) introduces the members of the inspection group, gets acquainted with the management and responsible persons of the inspected entity, announces the objectives and scope of the inspection, clarifies the inspection program and schedule, makes a confidentiality statement and answers questions from the inspected party.

During the inspection, changes and/or additions are made to the inspection program when nonconformities are identified that pose a high risk to product quality, process or quality system, in agreement with the subject of inspection.

21. The inspection team during the inspection:

1) carries out familiarization with documentation and records, requests information from the subject of inspection on the inspection of the facility regarding the requirements of the declared good pharmaceutical practice, conducts inspections of production, warehouse

premises, quality control zones, interviewing personnel of the inspected facility and monitoring the activities at the workplaces of personnel.

Russian Russian entities located outside the territory of the Republic of Kazakhstan submit documentation in Kazakh or Russian and ensure the presence of a certified and (or) licensed translator who translates from the language of the country of the subject into Kazakh or Russian languages;

2) if there is information indicating a decrease in the quality of the medicinal product, selects and conducts laboratory tests of samples of medicinal products. At the same time, the cost of samples is not subject to compensation;

3) performs audio and (or) video recording and photography, as well as makes copies of documents that are used as evidence in identifying inconsistencies with the requirements of good pharmaceutical practices;

4) receives clarifications from the inspection subject on issues arising during the inspection;

5) terminates an inspection if it is obstructed by the inspection subject and (or) the conditions for conducting the inspection are not provided;

6) takes measures or informs the subject of inspection about the need to take measures with respect to items (material evidence) that do not meet the requirements of the rules of good pharmaceutical practices, including with regard to restricting access to such items and ensuring their safety for further investigation.

22. Inconsistencies are divided into critical, essential and non-essential.

A critical non-compliance is non-compliance with the requirements of good pharmaceutical practice, which causes or leads to a significant risk of the possibility of reducing the quality of a medicinal product, the production of a medicinal product in the process of its circulation, dangerous to human health and life.

A significant nonconformity is a nonconformity with the requirements of good pharmaceutical practice, which is not classified as critical, causing or leading to a significant decrease in the quality of a medicinal product during its circulation, or a combination of nonconformities, none of which is significant in itself, collectively representing a significant nonconformity.

An insignificant nonconformity is a nonconformity that does not fall under the category of critical or significant, but is a violation of the requirements of declared good pharmaceutical practice or a nonconformity for which there is insufficient information to classify it as significant or critical.

23. In case of non-compliance with the requirements of good clinical practice (GCP), the following classification is applied:

Critical inconsistencies are 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 source documents.

Significant inconsistencies are conditions, practices, or processes that have adverse effects on the rights, safety, or well-being of subjects and/or on the quality and integrity of data, as well as include a set of deviations and/or numerous minor observations.

Non–material inconsistencies are conditions, practices, or processes that are not expected to adversely affect the rights, safety, or well-being of subjects and/or the quality and integrity of data.

24. The inspection ends with a final meeting with the responsible persons of the inspection subject, at which the lead pharmaceutical inspector (team leader) informs about the results of the inspection, listing all nonconformities identified during the inspection (if any).

25. If critical inconsistencies with the requirements of good pharmaceutical practices are identified, the inspection continues.

The leading pharmaceutical inspector (head of the group) sends relevant information to the state body on the identified critical inconsistencies, on the basis of which the state body makes a decision provided for by the requirement of subparagraph 8) of paragraph 3 of the Suspension Rules, which is notified in writing by the subject of inspection, and also, the state body notifies law enforcement agencies and customs control authorities to take appropriate measures.

26. When critical inconsistencies are identified, the subject of inspection is recognized by the state body as not meeting the requirements of the declared good pharmaceutical practice.

27. Based on the results of the inspection, the inspection team draws up a protocol of nonconformities in accordance with Annex 5 to these Rules, which contains a brief description of the nonconformities identified during the inspection.

28. The protocol of nonconformities, drawn up in two copies, is signed by the inspection team and the head of the inspection subject, one is transferred to the inspection subject, the other to the pharmaceutical inspectorate in electronic form within one calendar day from the moment of its signing, followed by its submission with a report on the pharmaceutical inspection (hereinafter referred to as the inspection report) in accordance with Annex 6 to these Rules.

29. The lead pharmaceutical inspector (team leader) shall prepare an inspection report no later than thirty (30) calendar days from the date of completion of the inspection.

The inspection report is drawn up in three (3) copies and signed by the lead pharmaceutical inspector (team leader) and members of the inspection team.

One copy of the inspection report is sent to the subject of inspection (with a cover letter) no later than 5 (five) calendar days from the date of its signing, the second copy is stored in the archive of the state body and the third copy is sent to the expert organization (when

conducting an inspection by an expert organization). During the GCP compliance inspection, the inspection report is sent to the sponsor of the clinical trial or the holder of the registration certificate.

Inspection documents are kept for 5 (five) years.

30. If significant and non-essential inconsistencies are identified, the subject of inspection, no later than 30 (thirty) calendar days from the date of receipt of the inspection report, sends a response to the pharmaceutical inspectorate and the head of the inspection group with an attachment of a plan of corrective and preventive actions and a report on its implementation.

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

32. The results of the assessment of the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation shall be coordinated by the leading pharmaceutical inspector (head of the group) with the state body within 5 (five) calendar days, with the exception of inspections specified in subparagraph 2) of paragraph 3 of these Rules.

33. One copy of the report on the assessment of the completeness and effectiveness of the corrective and preventive action plan and the report on its implementation by the state body is sent to the inspected entity (with a cover letter) no later than 10 (ten) calendar days from the date of its signing, the second copy is stored in the archive of the pharmaceutical inspectorate and the third copy is in the expert organization (when conducting inspections by an expert organization), with the exception of inspections specified in subparagraph 2) of paragraph 3 of these Rules.

34. When sampling (samples) of raw materials, materials or products, an inspection report is drawn up after receiving the test results from the testing laboratory. In this case, the period specified in paragraph 30 of these Rules begins to be calculated from the date of receipt by the state body, territorial subdivision or expert organization of the test results.

35. In order to obtain a certificate of compliance with the requirements of good manufacturing practice (GMP) and good distribution practice (GDP), the inspection subject who has received a notification letter on completion of the review of the corrective and preventive action plan and a report on its implementation submits an application in accordance with the procedure defined in Chapter 4 of these Rules.

36. The state body coordinates the activities of the pharmaceutical inspectorate for good pharmaceutical practices and issues or revokes a certificate of compliance with the requirements of good pharmaceutical practices in the field of drug circulation (hereinafter referred to as the certificate) in accordance with Annexes 7 and 8 to these Rules or a conclusion.

The certificate is issued for compliance with the requirements of good manufacturing practice (GMP) (except in cases of inspection within the framework of expert work), good distribution practice (GDP), good pharmacy practice (GPP), good laboratory practice (GLP).

The report (conclusion) is issued for compliance with the requirements of good clinical practice (GCP), good Pharmacovigilance practice (GVP).

Territorial divisions of the state body issue or revoke a certificate of compliance with the requirements of good pharmacy practice (GPP).

37. The certificate is issued on the basis of the application of the inspection subject, subject to the elimination of significant inconsistencies, as well as non-essential inconsistencies, if collectively they constitute significant inconsistencies.

Validity period of the certificate of compliance of the object with the requirements:

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

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

3) Good Pharmacy practice (GPP) – the first two times for 5 (five) years, with subsequent confirmation – indefinitely.

38. The subject of inspection is recognized as non-compliant with the requirements of the declared good pharmaceutical practice in the following cases:

1) when identifying critical inconsistencies;

2) failure to eliminate identified inconsistencies based on the results of the inspection with the attachment of a plan of corrective and preventive actions and a report on its implementation;

3) in case of failure to provide a response within the time limit established by paragraph 30 of these Rules;

4) if the subject of the inspection prevents the inspection;

5) if the subject of the inspection fails to carry out an inspection by decision of the authorized body.

A reasoned refusal to issue a certificate of compliance with the requirements of good pharmacy practice (GPP) and good laboratory practice (GLP) is sent to the subject of inspection in writing.

The inspection subject who submitted for compliance with the requirements of good manufacturing practice (GMP) of good and distribution practice (GDP), a reasoned refusal to provide a public service is sent in accordance with Annex 9 to these Rules, or, during an inspection within the framework of an examination of medicines, a negative conclusion on the safety, efficacy and quality of a medicinal product is issued in the form, installed in Appendices 14 and 15, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated January 27, 2021 № KR DSM-10 "On approval of the rules for the examination of medicines and medical devices" FF (registered in the Register of State Registration of Regulatory Legal Acts under № 22144).

39. Data on inspection subjects who have received a certificate shall be entered within 3 (three) working days by a structural subdivision of a state body or its territorial subdivision into the Register of Certificate Holders for Compliance with Appropriate Pharmaceutical Practices (hereinafter referred to as the register of certificate holders) in accordance with Annex 10 to these Rules for a period corresponding to the validity period of the certificate.

40. In case of changing the name of the subject, changing the name of the location address without physically moving the object, the subject of inspection 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 conclusion within 5 (five) business days.F

For certificates of compliance with good manufacturing practice (GMP) and good distribution practice (GDP), the data specified in this paragraph shall be reissued within 2 (two) business days after submitting the application in accordance with Annex 11 to these Rules.

41. The state body or its territorial subdivision shall issue a duplicate within 5 (five) working days from the date of receipt of the application if the certificate is lost by the subject of inspection for compliance with good pharmacy practice (GPP), good laboratory practice (GLP) or an opinion on compliance with the requirements of good clinical practice (GCP), good pharmacovigilance practice (GVP).

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

Based on the nature of the changes, the pharmaceutical Inspectorate decides within 15 (fifteen) calendar days to conduct a new inspection to verify compliance with the requirements of good pharmaceutical practices.

A footnote. Paragraph 42 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 04/14/2023 № 71 (effective ten calendar days after the date of its first official publication).

43. The state body or its territorial subdivision revokes the certificate or conclusion in the following cases:

1) at the request of the inspection subject;

2) identification of critical inconsistencies during inspection at the request of the subject of inspection to expand the scope of compliance with the standard;

3) liquidation of a subject in the field of circulation of medicines, medical devices;

4) identification of critical inconsistencies based on the results of an investigation conducted on the basis of appeals from individuals and legal entities to the state body on the

sale of low-quality products, non-compliance with the requirements of appropriate pharmaceutical practices during transportation and storage of medicines;

5) failure by the subject of inspection to submit an application within 30 (thirty) calendar days after the completion of the cases provided for in paragraph 5 of these Rules;

6) in case of identification of critical inconsistencies and failure to eliminate the identified inconsistencies based on the results of the inspection, 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 having a certificate of compliance with good manufacturing practice (GMP) without inspection;

7) when critical inconsistencies are identified and the identified inconsistencies are not eliminated according to the results of the inspection, with the attachment of a plan of corrective and preventive actions and a report on its implementation during the repeated inspection.

44. The certificate or conclusion shall cease to be valid on the basis of a revocation by a state body or its territorial subdivision, as well as upon expiration of the validity period of the certificate or conclusion.

The revoked certificate or conclusion shall be returned to the state body or its territorial subdivision within 5 (five) calendar days from the date of receipt by the inspection subject of the notification of revocation of the certificate.

45. Information on certificates issued, suspended and revoked by a state body or its territorial subdivision shall be entered into the register of certificate holders for compliance with appropriate pharmaceutical practices in accordance with Annex 10 to these Rules and posted on the Internet resource of the state body or its territorial subdivision.

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

46. In order to carry out an inspection for compliance with the standard of good manufacturing practice (GMP), the subject of inspection provides a list of medicines produced at the production site (planned for production) of the manufacturer or foreign manufacturer in respect of which the inspection is carried out, in accordance with Annex 12 to these Rules.

47. In order to conduct a remote inspection for compliance with the requirements of good manufacturing practice, the subject of inspection provides documents in accordance with Annex 13 to these Rules.

48. When the manufacturer transfers part of the production process and (or) contract analysis to another person (outsourcing), an additional inspection of the outsourcing organization is carried out, information about which is indicated in the manufacturer's statement and the manufacturer provides a visit to the outsourcing organization.

49. The issuance of a certificate of compliance with good manufacturing practice (GMP) is carried out without inspection for manufacturers of medicines of the Republic of Kazakhstan licensed for pharmaceutical activities related to the production of medicines on the basis of an application and a letter of guarantee for the provision of documents in accordance with paragraph 11 of these Rules submitted before July 1, 2021.

If the inspection subject fails to submit an application in accordance with paragraph 11 of these Rules by July 1, 2022, the certificate issued in accordance with this paragraph shall be revoked.

50. Pharmaceutical inspections for compliance with the Standard of Good Laboratory Practice (GLP) (hereinafter – GLP inspection) are carried out in accordance with the requirements approved by Order of the Minister of Health of the Republic of Kazakhstan dated November 4, 2020 № KR DSM-181/2020 "On Approval of the Rules for the Evaluation of Materials and Compliance of Preclinical (non-clinical) research Conditions with the Requirements of Good Laboratory Practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union within the framework of the Pharmaceutical Inspection Union" (registered in the Register of State Registration of Normative Legal Acts under № 21596).

51. The procedure for conducting a GLP inspection and forming a report on the results of a preclinical study or as part of expert work during registration, re-registration and making changes to the registration dossier is carried out and executed in accordance with Appendix 1 to the Rules of Pharmaceutical Practices, as well as in accordance with Decision № 81 of the Council of the Eurasian Economic Commission dated November 3, 2016 "On approval of the Rules of Good laboratory practice of the Eurasian Economic Union in the field of circulation of medicines".

52. Pharmaceutical inspections for compliance with the Standard of Good Clinical Practice (GMP) (hereinafter – GP inspection) are 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 № KR DSM-248/2020 "On approval of the rules for conducting clinical trials of medicines and medical devices, clinical and laboratory tests of medical devices for diagnostics outside a living organism (in vitro) and requirements for clinical databases and provision of state service Issuance of a permit for conducting a clinical trial and (or) testing of pharmacological and medicinal products, medical devices" (registered in the Register of State Registration of Regulatory legal Acts under № 21772).

53. GCP inspections are carried out at the clinical center in the premises of the sponsor and (or) the contract research organization (hereinafter referred to as the CIO), as well as in organizations related to the study.

54. GCP inspections are carried out in case of identified observations during the examination of clinical trial materials specified in Annex 14 to these Rules.

55. When conducting GCP inspections, an inspection dossier is formed in accordance with Annex 15 to these Rules and a report on inspections in accordance with Annex 16 to these Rules.

56. Pharmaceutical inspections for compliance with the Standard of Good Pharmacovigilance Practice (GVP) (hereinafter – GVP inspection) are 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 № KR DSM-320/2020 "On approval of the rules for conducting Pharmacovigilance and monitoring the safety, quality and effectiveness of medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 21896), the standard of good Pharmacovigilance practice (GVP) Rules of Pharmaceutical Practices, and also in accordance with the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 № 87 "On Approval of the Rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union".

Chapter 4. The procedure for the provision of public services "Issuance of certificates of compliance with appropriate pharmaceutical practices"

57. The state service "Issuance of certificates for compliance with the requirements of good pharmaceutical practices" (hereinafter – the state service) is provided by a state body (hereinafter – the service provider) to individuals and legal entities (hereinafter – the service recipient).

To receive a public service, the service recipient, after receiving a notification letter on the completion of consideration of the corrective and preventive action plan and a report on its implementation, submits an application in accordance with Annex 11 to these Rules through the e-government portal www.egov .kz, www.elicense.kz (hereinafter referred to as the Portal):

1) to obtain a certificate of compliance with the requirements of good manufacturing practice (GMP) in accordance with Annex 7 to these Rules;

2) to obtain a certificate of compliance with the requirements of good distribution practice (GDP), in accordance with Annex 8 to these Rules.

The basic requirements for the provision of public services, as well as the refusal to accept an application, including the characteristics of the process, form, content and result of the provision and other information, taking into account the specifics of the provision of public services, are given in the List of basic requirements for the provision of public services " Issuance of certificates of compliance with appropriate pharmaceutical practices" in accordance with Annex 17 to these Rules (hereinafter – a list of basic requirements).

58. On the day of receipt of the application and documents on the portal, the Service provider accepts and registers them.

When the service recipient applies after the end of working hours, on weekends and holidays, according to the Labor Legislation of the Republic of Kazakhstan, the application is accepted and the result of the provision of public services is issued on the next working day.

59. Through the portal – in the "personal account" of the service recipient, the status of acceptance of the application for the provision of public services and (or) notification indicating the date and time of receipt of the result of the provision of public services is displayed.

The service provider within 2 (two) working days reviews them for compliance with the list of basic requirements in accordance with Annex 17 of these Rules, based on the results of the review, forms one of the following results of the provision of public services:

a certificate of compliance with the requirements of good manufacturing practice (GMP);

certificate of compliance with the requirements of good distribution practice (GDP);

reasoned refusal to provide public services in accordance with Annex 9 to these Rules.

The result of the provision of public services is sent through the portal to the "personal account" of the service recipient in the form of an electronic document signed by the EDS of the head of the service provider, or a person replacing him.

60. The total period for the provision of the state service "Issuance of certificates for compliance with appropriate pharmaceutical practices" by the service provider is 2 (two) working days.

61. The service provider ensures that data on the provision of public services "Issuance of certificates of compliance with appropriate pharmaceutical practices" is entered into the information monitoring system in order to monitor the provision of public services in accordance with subparagraph 11) of paragraph 2 of Article 5 of the Law.

62. The authorized body sends information on the amendments and (or) additions to the subordinate regulatory legal acts defining the procedure for the provision of public services to organizations that accept applications and issue the results of the provision of public services, and to service providers (in accordance with the Register of Public Services), including the Unified Contact Center.

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

63. A complaint against the decision, actions (inaction) of employees of the structural divisions of the service provider is submitted to the head of the service provider and (or) to the authorized body for assessment and quality control of public services (hereinafter referred to as the body considering the complaint) in accordance with the legislation of the Republic of Kazakhstan.

Consideration of a complaint regarding the provision of public services is carried out by a higher administrative body, an official, or the body considering the complaint.

The complaint is submitted to the service provider and (or) the official whose decision, action (inaction) is being appealed.

64. The service provider, the official whose decision, action (inaction) is being appealed, no later than 3 (three) working days from the date of receipt of the complaint, send it to the body considering the complaint.

At the same time, the service provider, official, decision, action (inaction) are appealed, have the right not to send a complaint to the body considering the complaint if it makes a decision or administrative action within 3 (three) working days that fully meets the requirements specified in the complaint.

65. The complaint of the service recipient received by the service provider, in accordance with paragraph 2) of Article 25 of the Law, is subject to consideration within 5 (five) working days from the date of its registration.

The complaint of the service recipient received by the body considering the complaint is subject to consideration within 15 (fifteen) working days from the date of its registration.

66. Unless otherwise provided by law, an appeal to the court is allowed after a pre-trial appeal.

Appendix 1
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

For domestic applicants

In _____
name of the state body

Application for pharmaceutical inspection of the facility

Please carry out an inspection:

_____
the target
is indicated on the object: _____
_____
at the address: _____
At the same time, we declare:
Data of the subject of inspection:
Name of the legal entity and (or) individual entrepreneur

_____
Legal address: _____

BIN/IIN _____
The address of the object: _____
____
Pharmaceutical activity license number and its appendices (if available):
_____
Phone, fax: _____
Email address: _____
Outsourcing data (if available) _____
Last name, first name, patronymic (if any): _____
position of the head: _____
Director _____
Last name, first name, patronymic (if any) signature
Authorized person of the inspection subject:
_____ _____
Last name, first name, patronymic (if any) signature

Appendix 2
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

For foreign applicants

In _____
name of the expert body

Application for pharmaceutical inspection of the facility

Please carry out an inspection _____
the target is indicated
on the object: _____
At the address: _____
At the same time, we declare:
Data of the subject of inspection:
Name of the legal entity and (or) individual entrepreneur:
_____
Legal address: _____
The address of the object: _____
____
Pharmaceutical activity license number and its appendices (if available):
_____

Phone, fax: _____
Email address: _____
Outsourcing data (if available) _____
Last name, first name, patronymic (if any) _____
position of the head: _____
Director: _____
Last name, first name, patronymic (if any) signature
Authorized person of the inspection subject:

_____ _____
Last name, first name, patronymic (if any) signature

Appendix 3
to the Rules
for Conducting Pharmaceutical
Inspections on Appropriate
Pharmaceutical Practices
Form

The list of documents submitted by the subject of inspection for pharmaceutical inspection

Footnote. Appendix 3 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 14.04.2023 № 71 (effective ten calendar days after the date of its first official publication).

№	Name of the document	The Standard of Good Pharmaceutical Practice					
		GMP	GDP	GLP	GCP	GVP	GPP
1	2	3	4	5	6	7	8
1	a notarized copy or an electronic copy of the current permit (license) for pharmaceuti cal activities or an extract from the relevant register of the country in which the inspected entity is located (for foreign applicants) (if available)	+	-	-	-	-	-

2	a notarized copy of the document confirming compliance with the requirements of the rules of good pharmaceutical practice (for foreign applicants) (if available)	+	-	+	+	+	-
3	a copy of the quality manual (the concept of management and development of the quality system of the subject of inspection)	+	+	-	-	+	+
4	a copy of the organizational structure and staffing of the facility	+	+	+	+	+	+
5	a copy of the dossier of the production site (site)	+	-	-	-	-	-
6	the list of medicines produced at the production site (planned for production) of the manufacturer or foreign manufacturer, in respect of which the inspection is carried out	+	-	-	-	-	-

7	a list of documented standard operating procedures in electronic form (on electronic media)	+	+	+	+	+	+
8	list of inspections for the last 5 (five) years	+	-	-	-	+	-
9	a copy of the report on the results of the last inspection (if available)	+	-	+	+	+	-
10	the master file of the pharmacovigilance system of the registration certificate holder	-	-	-	-	+	-
Documents are provided in Kazakh and (or) Russian languages							

Appendix 4
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

Pharmaceutical inspection program

1. Name of the inspection subject _____
2. The basis for the inspection _____
3. Purpose of the inspection _____

___

4. Date of inspection _____
5. Name of the object _____
6. The location of the object _____
7. Composition of the inspection team and responsibilities:

№	Surname, first name, patronymic (if any)	Position, place of work

	of pharmaceutical inspectors	
1		

Each of the above-mentioned persons visiting this enterprise is responsible for the confidentiality of information that may become known to them during the inspection.

8. Inspection procedure _____

9. Subject of inspection _____

10. Necessary conditions _____

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

_____

11. Procedures _____

12. Inspection schedule:

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

Appendix 5
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

Protocol of inconsistencies

From "__" _____ ____ year

Name of the inspection subject

_____

The object of activity _____

Identified inconsistencies	A brief description of the identified inconsistencies	Note
Critical		
Significant		
Non- essential		

Leading Pharmaceutical Inspector (Team Leader)

_____ _____

Last name, first name, patronymic (if any) signature

Members of the inspection team

_____ _____

Last name, first name, patronymic (if any) signature

_____ _____

Last name, first name, patronymic (if any) signature

Head of the inspection entity

_____ _____

Last name, first name, patronymic (if any) signature

Authorized person of the inspection subject

_____ _____

Last name, first name, patronymic (if any) signature

Appendix 6
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

Pharmaceutical Inspection Report

Name of the Pharmaceutical Inspectorate

_____

address, phone, website _____

Name of the inspection subject _____

Address _____

Footing _____

1. Summary

Name of the inspected object	The name and full address of the object
License	
Types of company activities	
Date of the inspection	
Information about inspectors (experts)	Last name, first name, patronymic (if any), position
Inspection number (if available)	

2. Introductory information

A brief description of the inspection subject and the inspected area.	
Date(s) of previous inspections	
Surname, first name, patronymic (if any), position of the inspectors who conducted the previous inspection	
Significant changes compared to the previous inspection	
Purpose of the inspection	
Inspected areas	
The personnel of the organization involved in the inspection	
Documents submitted by the inspection subject prior to the inspection	

3. Observations and inspection results.

For GMP compliance inspections:

Quality Management	
Staff	
Premises and equipment	
Documentation	
Production	
Quality control	
Outsourcing activities	
Product complaints and recalls	
Self-inspection	
Sales and transportation of products	
Evaluation of the dossier of the production site	
Various	

For inspections of compliance with the requirements of Good Pharmacy Practice (GPP) and good distribution practice (GDP), the relevant sections of the rules of good pharmaceutical practices are filled in.

4. List of identified inconsistencies *

Critical	
Significant	
Non-essential	

Note*

A critical non-compliance is non-compliance with the requirements of good pharmaceutical practice, which causes or leads to a significant risk of the possibility of reducing the quality of a medicinal product, the production of a medicinal product in the process of its circulation, dangerous to human health and life.

A significant nonconformity is a nonconformity with the requirements of good pharmaceutical practice, which is not classified as critical, causing or leading to a significant decrease in the quality of a medicinal product during its circulation, or a combination of nonconformities, none of which is significant in itself, collectively representing a significant nonconformity.

An insignificant (other) nonconformity is a nonconformity that does not fall under the category of critical or significant, but is a violation of the requirements of declared good pharmaceutical practice or a nonconformity for which there is insufficient information to classify it as significant or critical.

5. Final meeting and assessment of the inspection subject's response:

Comments made by representatives of the inspection subject during the final meeting		
Assessment of the inspection subject's response to the identified inconsistencies		

Documents and/or samples selected during the inspection		

6. Inspection results and recommendations:

Inspection results	
Recommendations	

The report on the pharmaceutical inspection was drawn up and signed by:
The Leading Pharmaceutical Inspector (head of the group)

_____ _____

Last name, first name, patronymic (if any) signature
Members of the inspection team

_____ _____

Last name, first name, patronymic (if any) signature

_____ _____

Last name, first name, patronymic (if any) signature
"_____" _____ _____ of the year.

Sections 7 and 8 are filled in by the inspection team after receiving information on the elimination of identified inconsistencies and coordination with the pharmaceutical inspectorate of the state body.

7. The results of the review of the elimination of identified inconsistencies and the conclusions of the inspection:

The list of identified inconsistencies	Qualification of identified inconsistencies	Information on the elimination of identified inconsistencies (summary of corrective and preventive actions, supporting document)	Assessment of the elimination of identified inconsistencies

8. Conclusion
The subject of the inspection, the name of the object, site, address

_____

Meets (does not meet) the requirements of good pharmaceutical practice (specify the name of good pharmaceutical practice).

Appendix 7
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN COMMITTEE FOR MEDICAL AND PHARMACEUTICAL CONTROL CERTIFICATE OF COMPLIANCE WITH THE REQUIREMENTS OF THE RULES OF GOOD MANUFACTURING PRACTICE OF THE EURASIAN ECONOMIC UNION.
№_____ (the registration number of the certificate)
The validity period is from _____ 202_. to _____202_ .

Issued following the results of a pharmaceutical inspection in accordance with the Rules of Pharmaceutical Inspections.
_____
(full or abbreviated name of the authorized body)
Confirms the following:
A pharmaceutical inspection has been carried out
_____
(full name of the manufacturer)
_____
(address of the production site)
based on (specify one of the following): statements №_____ to obtain a permit (license) to carry out activities for the production of medicines; the plan for conducting pharmaceutical inspections, as the holder of a permit (license) for the production of medicines №_____; statements №_____ for registration of medicines; _____ ____ (other reason)
Based on the information obtained during the pharmaceutical inspection, the last of which was carried out from _ ____ to _____ 202_year, it is considered that this pharmaceutical manufacturer complies with the requirements of the Rules of Good Manufacturing Practice of the Eurasian Economic Union.
This certificate reflects the status of the production site at the date of the pharmaceutical inspection and after 3 years from the date of this pharmaceutical inspection should not be accepted as a document certifying the status of compliance. The validity period of the certificate may be shortened or extended by using appropriate risk management principles, if there is an appropriate entry about this in the field "Restrictions or explanatory notes concerning the scope of this certificate".
The certificate is valid when all its pages (both main sheets and additional sheets) are submitted.
The authenticity (authenticity) of this certificate can be checked in the database
If the certificate is not presented in the specified database, you should contact the authorized body that issued it.

	X	Medicinal products for medical use
		Veterinary medicines
		Experimental tools
Production and quality control Production operations – medicinal products		

1. Sterile products

	1) Products prepared aseptically (processing operations for the following dosage forms):	
		high volume liquid dosage forms
		liquid dosage forms of small volume
		variances
		lyophilizates
		solid dosage forms and implants

		mild dosage forms										
					(specify the type of product or activity)							
	2) Products undergoing final sterilization (processing operations for the following dosage forms):											
		high volume liquid dosage forms										
		liquid dosage forms of small volume										
		solid dosage forms and implants										
		mild dosage forms										
		other products, dosage forms										
						(specify the type of product or activity)						
	3) Releasing quality control											
2. Non-sterile products												
	1) Non-sterile products (processing operations for the following dosage forms):											
		capsules in a hard shell										
		soft-shell capsules										
		chewable dosage forms										
		impregnated dosage forms										
		liquid dosage forms for external use										
		liquid dosage forms for internal use										
		medical gases										
		other solid dosage forms										
		drugs under pressure										
		radionuclide generators										
		mild dosage forms										
		candles (suppositories)										
		Pills										

		transdermal patches										
		devices for intraruminal (intrauterine) administration										
		other products, dosage forms										
					(specify the type of product or activity)							
	2) Releasing quality control											
3. Biological medicinal products												
	1) Biological medicinal products:											
		blood products										
		immunological products										
		somatic cell-based products										
		gene therapy products										

tissue engineering products

biotechnological products

products extracted from animal sources or human organs (tissues)

(specify the type of product or activity)

2) Manufacturing quality control (list of product types):

blood products

immunological

products somatic cell-based

products gene

therapy products tissue engineering

products biotechnological products

products extracted from animal sources or human organs (tissues)

(specify the type of product or activity)

4. Other products or production activities

1) Production:

herbal products

homeopathic products

(specify the type of product or activity)

2) Sterilization of active substances, excipients, finished products:

filtration

dry-burning sterilization

steam sterilization

chemical

sterilization gamma radiation

sterilization electronic radiation sterilization

3)

_____

(specify the type of product or activity)

4) Primary (internal) packaging:

capsules in a hard shell

soft-coated capsules

chewable dosage forms

impregnated dosage forms

liquid dosage forms for external use

liquid dosage forms for internal use

medical gases

other solid dosage forms

drugs under pressure

radionuclide generators

		soft dosage forms			
		candles (suppositories)			
		tablets			
		transdermal patches			
		devices for intraruminal (intrauterine) administration			
					(specify the type of product or activity)
		5) Secondary (consumer) packaging			
		6) Releasing quality control			
		7) Microbiological testing: sterility			
		8) Microbiological testing: non-sterility			
		9) Chemical (physical) testing			
		10) Biological testing			
		Quality control during the import of medicinal products			
	1. Quality control of imported medicinal products:				
		Microbiological testing: sterility			
		Microbiological testing: non-sterility			
		chemical (physical) testing			
		biological testing			
	2. Release control (series certification) of imported products				
	Sterile products:				
		products prepared aseptically			
		products undergoing final sterilization			
	Non-sterile products				
	Biological medicinal products:				
		blood products			
		immunological			
		products somatic cell-based			
		products gene			
		therapy products tissue engineering products			
		Page 4 of 5			
		№_____ (registration number of the certificate)			
		biotechnological products			
		products extracted from animal sources or organs (tissues)			
					(specify the type of product or activity)
	3. Other import (import) activities:				
		site of physical import (import)			
		import of an intermediate product undergoing further processing			
					(specify the type of product or activity)

Restrictions or explanatory notes concerning the scope of the certificate:

(Full name (if any), position) _____ (signed)

P.P.

_____

(registration number of the form)

Page 5 of 5

*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 medicines.

Appendix 8
to the Rules for Conducting
Pharmaceutical Inspections
on Appropriate
Pharmaceutical Practices
Form

MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN COMMITTEE FOR MEDICAL AND PHARMACEUTICAL CONTROL CERTIFICATE OF COMPLIANCE WITH THE REQUIREMENTS OF GOOD PHARMACEUTICAL PRACTICES IN THE FIELD OF DRUG CIRCULATION

№ _____

Date of issue "____" _____ ____ year

Valid until "____" _____ ____ year

Issued _____

(full name, location of the object)

_____

(name of the object)

Based on the information obtained during the pharmaceutical inspection, the last of which was carried out "____" _____ 20____ year and confirms compliance

_____

(standard of good pharmaceutical practice)

The State body that issued the certificate

_____

(full name)

Head of the State body

_____ _____

Last name, first 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 medicines.

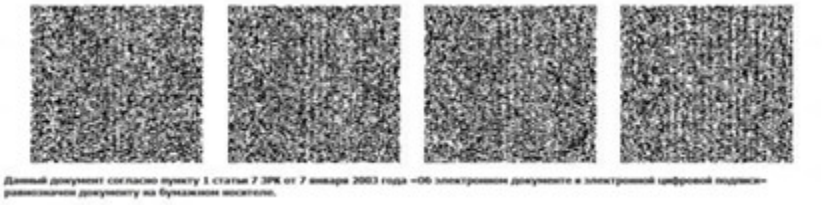
Appendix 9
to the rules for conducting
pharmaceutical inspections
on appropriate

pharmaceutical practices
Form

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

Motivated refusal to provide a public 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 from [Date]
The reason for the refusal:
[Reason for refusal] [Position of the signatory]
[Surname, first name, patronymic (if any) of the signatory]



[Position of the signatory] [Surname, first name, patronymic (if any)]

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

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

№	Name, legal address, phone number of the certificate holder	Address of the certificate holder's facility	Certificate number, date of issue, validity period	The area of compliance with standards	Information about the suspension and revocation of the certificate

1	2	3	4	5	6

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

Application for the issuance or reissue of a certificate of compliance with good pharmaceutical practices

In _____
(name of the state body)
Please issue or reissue a certificate of compliance with the requirements
of Good Manufacturing practice (GMP) or Good Distribution
Practice (GDP)

_____
(underline it)
to the object: _____
(full name of the object)
located at: _____
(address of the object)
Data of the inspection subject:
Name of the legal entity and (or) individual entrepreneur

_____
Legal address: _____
BIN/IIN _____
Pharmaceutical activity license number and its appendices (if available):

_____
Phone, fax, e-mail: _____
Email address: _____
The name of the subject, changing the name of the location address
without physically moving the object when changing (for re-registration)

_____
Information about the applicant _____
_
(Developer, Manufacturer (manufacturer), Distributor, Trustee)
Location address (phone, fax, e-mail) _____
Date and number of the power of attorney (copy of the power of attorney) _____
_____
(When registering an application through the electronic version portal)

Inspection period _____

For production: _____

(product type)

Dosage form _____

Director _____ _____

Last name, first name, patronymic (with his signature)

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

The list of medicines produced at the production site (planned for production) of the manufacturer or foreign manufacturer, in respect of which the inspection is carried out

The trade name of the medicinal product or the name of the pharmaceutical substance	International nonproprietary name or grouping (chemical) name of a medicinal product or pharmaceutical substance	Dosage form, dosage (if available)	Registration certificate, date of issue, validity period or registry entry, date of inclusion in the registry for an active pharmaceutical substance (if available)	Product type (specified in accordance with Appendix № 3)

Date of compilation "____" _____ 20____ of the year.

The head of the company or an authorized representative (position)

_____ _____

Last name, first name, patronymic (if any) signature

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

The list of documents submitted by the subject of inspection for remote inspection for compliance with the requirements of good manufacturing practice

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

2. Dossier of the production site (master file – SMF website), compiled in accordance with the standard of good manufacturing practice of the Republic of Kazakhstan or the GMP

PIC/S manual (complete or updated 6 (six) months before the date of the pharmaceutical inspection; information on planned changes).

3. Diagrams attached to the SMF (color schemes of the water and air treatment system, diagrams of pipelines and equipment in A3 or A2 format).

4. A list of manufactured medicines (a list of product types, trade names and international nonproprietary names, a list of production stages declared for inspection).

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

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

7. Qualification master plan (list of premises, equipment and auxiliary systems used for production and their qualification status).

8. Validation master plan (production processes, cleaning and quality control).

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

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

11. Information on the number of rejected batches of all medicines.

12. A list of critical, significant nonconformities, deviations from the specification (Out-of-specification) (hereinafter referred to as OOS) for the previous 3 (three) years (reports on nonconformities, OOS of the process (including revised series) that affected the quality, safety and effectiveness of medicines).

13. A list of planned and completed CAPA (corrective and preventive action) after inspections over the previous 3 (three) years (including inspections of the Member States of the Union).

14. A letter of guarantee from an authorized person of the manufacturer stating that the production site has been fully checked according to GMP requirements over the past 2 (two) years and the identified inconsistencies have been eliminated.

15. Product quality reviews.

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

Comments on the examination of clinical trial materials

1) the quality of the dossier	missing documents (for example, lack of GCP declaration, lack of audit certificates, lack of information about the monitoring process);
	inconsistency of the data;
	this applicant has had problems with the quality of the dossier in the past
2) type of drug (recombinant drug, cell therapy, gene therapy, active substance that is a new chemical compound, blood preparation, orphan drug, other);	
3) the applicant and (or) the sponsor and (or) the CIO (to which the main and (or) relevant parts of the research were delegated):	first application from a new applicant
	previous inspection experience (never inspected and/or for a long time after the last inspection and/or inspection with a negative result);
4) target population (children, other vulnerable, critically ill patients, emergencies, all types)	
5) information from the authorities of third countries about the negative outcome of inspections (for example, the US FDA, EMA, others);	
6) the location of the country in which the clinical trial was conducted, outside the territories of the ICH countries .	
7) ethics	lack of information about the examination by the ethics committee of all or some of the documents of the clinical trial (for example, protocol, information for the subject and informed consent, procedures for involvement) and research centers;
	the lack of a description of the ethical aspects of the study (for example, the inclusion of vulnerable patients, the high incidence of illiteracy in the study population, the requirement of a witness) and the problems encountered (if any);
	the failure of the informed consent process or information provided to the subjects of the study
8) researchers and the administrative structure of the study: a complex administrative structure (for example, the participation of a large number of contract research organizations and (or) suppliers, subcontractors)	
9) research plan	study design factors (for example, the complexity of the study design, insufficient justification for the use of placebo and/or the choice of an active comparator);
	significant protocol changes during the study (for example, changes in primary endpoints or statistical methods or criteria for inclusion and/or non-inclusion) and/or a large number of amendments to the protocol;
	Intervention factors: the authenticity and characteristics of the investigational drug and interventions are unclear: 1) contradictions between the protocol and the research report regarding dosage forms, packaging, labeling, storage conditions, dose, dosage regimen and duration; 2) special susceptibility to instability of the studied medicinal product under improper storage or transportation conditions; 3) preparation by pharmaceutical and (or) clinical workers before administration;

	4) modification of the drug during the study; 5) Complex titration or dose escalation;
10) criteria and data for evaluating effectiveness 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 carried out
	Clinical outcome assessment: If someone other than the researcher was responsible for evaluating clinical outcomes (for example, a sponsor, external evaluators, or an external committee), the following elements of the data movement process should be considered: appropriate instructions and/or training of researchers to collect and report performance parameters; identification data and independence of external appraisers and/or the committee; procedures for preparing, reviewing, evaluating, and documenting outcomes, including ways to maintain blindness.
11) statistical methods	changes in statistical methods and/or endpoints at the time and/or after the study, in particular changes made before the removal of blindness, and/or unplanned statistical analysis;
	the data of the patient(s) are excluded from the analysis unreasonably or on grounds of concern, in particular if the results are favorable to the test drug or if the decision(s) to exclude the data is made after the data has been sent out.
12) implausibility and/or inconsistency of the provided clinical data:	the results contradict the known literature data or other research results;
	data with an unusual trend or abnormal amount of variation or extremely small deviations (i.e. high or low variability of efficacy parameters that have high or low natural variability; unexpectedly low rates of reports of (serious) adverse events or concomitant medications);
	inconsistent, incorrect or incomplete registration and reporting of data: incorrect design of the individual registration card (hereinafter referred to as the IRC) (for example, amendments to the protocol are not reflected in the IRC); lack of relevant data lists; inconsistency between patient data lists and deported data in the clinical trial report; a large number of missing values.

Appendix 15
to the Rules for conducting
Pharmaceutical inspections
on appropriate
pharmaceutical practices

Form

The format of the inspection dossier

1. Content
2. Contacts:
1) with the requesting party;
2) with the lead inspector(s) and participating inspectors;
3) with appraisers;
4) with the applicant and/or sponsor;
5) with the inspected persons.
3. Documents related to the study (if available)
Provided by the applicant and/or sponsor:
1) Protocol and amendments;
2) Clinical trial report;
3) The researcher's brochure;
4) blank forms of informed consent of patients;
5) Patient list and audit trails.
Provided by an expert (appraiser):
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) the composition of the inspection team (central and for each selected center);
3) contracts;
4) Research planning documents.
5. Locally collected information of general importance
Documents seized or copied during the inspection.
6. Inspection reports
Inspection reports (including responses from the inspected person(s) and evaluation of the summary inspection report (final version).

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

Report on the pharmaceutical inspection for compliance with good clinical practice

Name of the Pharmaceutical Inspectorate

_____

address, phone, website _____

Name of the inspection subject _____

Address _____

Footing _____

1. Summary

The name of the inspected object (underline it): KIO Sponsor Clinical base(s)	The name and full address of the object
License	
Types of company activities	
Date of the inspection	
Information about inspectors (experts)	Last name, first name, patronymic (if any), position
Inspection number (if available)	
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 research databases	
The timing of the study	
Information about the Sponsor: name and address of the organization Full name of the contact person	
Information about the Applicant: Sponsor The official representative of the Sponsor The person or organization authorized by the sponsor to submit this application (in this case, specify the full name of the contact person, address, contact details (phone, fax, e-mail)	
Clinical(their) base	Name and address
For bioequivalence research	Name and address of the bioanalytical part of the CI
Inspection Details	
Date of the event	
Type of inspection: Planned or unplanned or repeated (order) online or offline; pre-registration or post-registration (specify the application number)	

2. Introductory information

A brief description of the inspection subject and the inspected area.

Date(s) of previous inspections

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

Significant changes compared to the previous inspection

Purpose of the inspection

Inspected areas

The personnel of the organization involved in the inspection

Documents submitted by the inspection subject prior to the inspection

3. Observations and inspection results.

For GCP compliance inspections:

Quality Management	
Staff	
Premises and equipment	
Documentation	
Archive	
Outsourcing activities	
Self-inspection	
Reports of adverse reactions or phenomena	
Evaluation of the main clinical trial dossier	
Management of the investigational drug	
Various	

4. Final meeting and assessment of the inspection subject's response:

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

Assessment of the inspection subject's response to the identified inconsistencies

Documents and/or samples selected during the inspection

5. Inspection results and recommendations:

Inspection results

Recommendations

The report on the pharmaceutical inspection was drawn up and signed by:

The Leading Pharmaceutical Inspector (head of the group)

_____ _____

Last name, first name, patronymic (if any) signature

Members of the inspection team

_____ _____

Last name, first name, patronymic (if any) signature

_____ _____

Last name, first name, patronymic (if any) signature

"_____" _____ _____ of the year.

Sections 6 and 7 are filled in by the inspection team after receiving information on the elimination of identified inconsistencies and coordination with the pharmaceutical inspectorate of the state body.

6. The results of the review of the elimination of identified inconsistencies and the conclusions of the inspection:

The list of identified inconsistencies	Qualification of identified inconsistencies	Information on the elimination of identified inconsistencies (summary of corrective and preventive actions, supporting document)	Assessment of the elimination of identified inconsistencies

7. Conclusion

The subject of the inspection, the name of the object, site, address

_____

Meets (does not meet) the requirements of good pharmaceutical practice (specify the name of good pharmaceutical practice).

Appendix 17
to the Rules for conducting
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The list of basic requirements for the provision of public services "Issuance of certificates for compliance with good pharmaceutical practices"

The name of the state service "Issuance of certificates for compliance with appropriate pharmaceutical practices" The name of the subspecies of the state service: 1) issuance of a certificate of compliance with the requirements of good manufacturing practice GMP); 2) issuance of a certificate of compliance with the requirements of good distribution practice (GDP).		
1	Name of the service provider	Committee of Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan
2	Ways of providing public services	For all subspecies: The e-government web portal: www.egov .kz, www.elicense.kz (hereinafter referred to as the portal)
3	The term of the provision of public services	For all subspecies: Certificate issuance - 2 (two) business days; Reissue – 2 (two) business days.
4	The form of public service provision	For all subspecies: Electronic (partially automated)/paper
		1) issuance or reissue of a certificate of compliance with the requirements

5	The result of the provision of public services	of good manufacturing practice (GMP); 2) issuance or reissue of a certificate of compliance with the requirements of good distribution practice (GDP); 3) a reasoned refusal to provide a public service in accordance with Appendix 9 to these Rules.
6	The amount of the fee charged to the service recipient for the provision of public services, and the methods of its collection in cases provided for by the legislation of the Republic of Kazakhstan	The public service is provided free of charge
7	The work schedule of the service provider and information objects	1) the 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) the portal – around the clock, except for technical breaks in connection with repair work (when the service recipient applies after the end of working hours, on weekends and holidays, according to the Labor Code of the Republic of Kazakhstan, the application is accepted and the result of the provision of public services is issued on the next working day).
8	The list of documents and information required from the service recipient for the provision of public services	To obtain a certificate of compliance with the requirements of good manufacturing practice (GMP) and (or) a certificate of compliance with the requirements of good distribution practice (GDP) – an application in accordance with Annex 11 to these Rules; To reissue a certificate of compliance with the requirements of good manufacturing practice (GMP) and (or) a certificate of compliance with the requirements of good distribution practice (GDP): 1) an application in accordance with Annex 11 to these Rules; 2) an electronic copy of the document confirming the change in the name of the subject, the change in the name of the location address

		without physically moving the inspection object (except for information available in the relevant information systems).
9	Grounds for refusal to provide public services established by the legislation of the Republic of Kazakhstan	1) establishing the unreliability of the documents submitted by the service recipient for receiving a public service, and (or) the data (information) contained therein; 2) non-compliance of the service recipient and (or) the submitted materials, data and information necessary for the provision of public services with the requirements of these Rules; 3) in case of non-compliance with the requirements of paragraph 57 of these Rules.
10	Other requirements, taking into account the specifics of the provision of public services	The service recipient has the opportunity to receive information about the procedure and status of the provision of public services in remote access mode through the portal - in the "personal account", as well as a single contact center. The contact numbers of the information services on the provision of public services 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 . The phone numbers of the unified contact center for the provision of public services are 1414, 8-800-080-7777.

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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