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 dated July 7, 2020 "On Public Health and Healthcare System", **I HEREBY ORDER:**

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, No. ҚР ДСМ-9

The Rules for Conducting Pharmaceutical Inspections on Good Pharmaceutical Practices

Chapter 1. General Provisions

1. These Rules for Conducting Pharmaceutical Inspections on Good Pharmaceutical Practices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 6 of Article 244 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and the healthcare system" (hereinafter referred to as the Code) and shall determine the procedure for conducting pharmaceutical inspections for good pharmaceutical practices.

2. The following definitions shall be used in these Rules:

1) state expert organization in the field of medicine circulation and medical devices (hereinafter referred to as the Expert organization) - a state monopoly entity that carries out production and economic activities in the field of healthcare to ensure the safety, efficacy and quality of medicines and medical devices;

2) good pharmaceutical practices in the field of medicine circulation (hereinafter referred to as Good pharmaceutical practices) - healthcare standards that apply to all stages of the medicine life cycle: 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) state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body) - the state body exercising management in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices;

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

5) pharmaceutical inspector for good 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;

6) pharmaceutical inspection for good pharmaceutical practices (hereinafter referred to as Inspection) - assessment of a facility in the field of circulation of medicines to determine its compliance with the requirements of good pharmaceutical practices of the Republic of Kazakhstan and (or) the Eurasian Economic Union.

3. The inspection shall be carried out for compliance of the object of the subject of inspection with the standards of good pharmaceutical practices approved in accordance with subparagraph 9) of Article 10 of the Code.

Inspections shall be carried out:

1) for compliance with the requirements of good laboratory practice (GLP), good clinical practice (GCP), good manufacturing practice (GMP), and good distribution practice (GDP) of

entities located on the territory of the Republic of Kazakhstan, by the state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body);

2) for compliance with the requirements of good pharmacy practice (GPP) by the 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) by an expert organization.

4. The state body shall coordinate the activities of the pharmaceutical inspectorate on good pharmaceutical practices.

The state body shall issue or withdraw certificates (conclusions) for compliance with the requirements of good pharmaceutical practices in the field of medicine circulation (hereinafter referred to as the Certificate).

Territorial divisions of the state body shall issue or withdraw certificates of compliance with the requirements of good pharmacy practice (GPP).

5. The expenses for organizing and conducting inspections of an expert organization shall be borne by the applicant based on an agreement concluded with an expert organization in accordance with the civil legislation of the Republic of Kazakhstan.

6. By decision of the state body, remote inspections shall be carried out for compliance with good manufacturing practice (GMP) and good distribution practice (GDP) on documents indicating the coordinates of the location by satellite using remote interaction tools, via audio or video communication without visiting the production facility based on the assessment documentation at facilities previously inspected, with a corresponding mark in the inspection report in the following cases:

1) in the event of a threat of occurrence, occurrence and liquidation of an emergency;

2) when there is a threat of the spread of a disease that poses a danger to others;

3) diseases and injuries resulting from exposure to an adverse chemical, biological, and radiation factors.

7. If the result of the remote inspection is positive after the restrictions provided for in paragraph 6 of these Rules are lifted, an inspection shall be carried out with a visit to the subject of inspection based on the application of the subject.

If the subject of inspection fails to apply within a month, the certificate issued as a result of the remote inspection shall be withdrawn.

8. To carry out the inspection, an inspection team shall be created, consisting of a chief pharmaceutical inspector (head of the team), team members, including pharmaceutical inspectors, involved experts and trainees.

9. The inspection team shall consist of two or more inspectors, including the chief pharmaceutical inspector.

The requirements for the inspection team, the qualification level of the employees of the pharmaceutical inspectorate and the experts involved in the work of the inspection team shall be established by the quality system procedures of the pharmaceutical inspectorate.

Interns may be included in the inspection team.

10. When conducting an inspection, inspectors shall not act as consultants, respect the confidentiality of information obtained in the course of preparing and conducting an inspection, and also keep the results of the inspection confidential.

Chapter 2. Procedure for Conducting Inspections

11. An inspection shall be carried out in the cases provided for in paragraph 3 of Article 244 of the Code.

12. To inspect for compliance with the requirements of good pharmaceutical practices in the field of medicine circulation, the subject of inspection shall apply to the inspectorate, in accordance with Annexes 1 and 2 to these Rules.

The subject of inspection shall attach the following documents to the application:

1) a copy of the license to carry out activities (if any);

2) a copy of the quality manual;

3) copies of the organizational structure and staffing of the facility;

4) a copy of the dossier of the production site (site) (for manufacturers);

5) a list of medicinal products manufactured at the production site (scheduled for production) of the manufacturer or foreign manufacturer, in respect of which the inspection is carried out (for manufacturers) according to the form in accordance with Annex 3 to these Rules;

6) copies of documented standard operating procedures in electronic form;

7) a copy of the report on the results of the last inspection (if any);

8) list of inspections for the last 5 years.

Documents shall be provided in Kazakh and (or) Russian.

13. The Pharmaceutical Inspectorate shall review the documents submitted in accordance with paragraph 12 of these Rules within 15 calendar days. If there are comments on the submitted documents, the subject shall eliminate these comments within 30 calendar days.

14. The appointment of an inspection shall be refused if the comments on the submitted documents are not eliminated within a period not exceeding 30 calendar days.

15. When conducting a remote inspection, the list of documents submitted by the subject of inspection during a pharmaceutical inspection without visiting the object of inspection, the subject inspection shall be included in the inspection program.

16. In case of transfer by the manufacturer of a part of the production process and (or) analysis under the contract to another person (outsourcing), an additional inspection of the

outsourcing organization shall be carried out, information about which shall be indicated in the manufacturer's application and the manufacturer shall provide a visit to the outsourcing organization.

17. To inspect during the examination of medicinal products, the expert organization, in the course of expert work during the registration of medicinal products, shall send a notification to the applicant about the need for an inspection and coordinate the composition of the inspection team with the state body.

18. Repeated inspections for confirmation by subjects that have received a certificate of compliance of the object with the requirements of good pharmaceutical practices in the field of circulation of medicines (hereinafter referred to as the Certificate) shall be carried out during the validity period of the certificate in accordance with the inspection schedule approved by the head of the state body. The frequency of inspections shall be determined based on risk assessment.

19. The Pharmaceutical Inspectorate shall include an application in the inspection schedule and sends electronic copies of the documents listed in paragraph 12 of the Rules to the inspection team.

The chief pharmaceutical inspector shall ensure the development of a program for the conduct of a pharmaceutical inspection (hereinafter referred to as the Inspection Program) in accordance with Annex 4 to these Rules. The inspection program shall be signed by the inspection team and sent to the subject of inspection seven calendar days before the start of the inspection at the facility.

20. The chief pharmaceutical inspector shall distribute functions in the inspection team and coordinate the preparatory activities.

21. The inspection team shall preliminary examine the documents submitted by the subject of inspection related to the inspected activity.

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

23. The inspection shall begin with an introductory meeting held in the presence of the head and responsible persons of the subdivisions of the subject of inspection, where the inspection program shall be discussed, and authorized persons of the subject of inspection shall be introduced.

The chief pharmaceutical inspector shall inform the subject of inspection on the purpose, timing, and content of the inspection, introduce the members of the inspection team, discuss organizational issues, and provide the subject of inspection with an opportunity to make a brief overview of the quality system and activities at the facility.

During the inspection, changes and (or) additions shall be made to the program in case of detection of inconsistencies that pose a high risk concerning the quality of the product, process or quality system.

24. The subject of the inspection shall cooperate with the inspection team and create conditions for the inspection. During the inspection, the inspected subject shall provide the inspection team with the necessary information, documents, and records, provide access to transport, production, storage, auxiliary premises, quality control rooms, as well as other premises of the subject, and interviews the responsible persons of the inspected subject and monitors their activities at workers places.

25. The inspection team during the inspection shall:

1) familiarize with documents and records, requests from the subject of inspection information on the inspection of the facility regarding the requirements of the declared good pharmaceutical practice, inspect production, storage facilities, quality control areas, interview the facility personnel and monitor the activities of the personnel workplaces;

2) if a decrease in the quality of the medicinal product is suspected, the selection and conduct of laboratory tests of samples of medicinal products shall be carried out;

3) perform audio or video recording and photography, as well as make copies of documents that may be used as evidence when discrepancies are identified;

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

5) terminate the inspection if it is obstructed;

6) take measures or require taking measures concerning items (material evidence) that may presumably indicate inconsistency with the requirements of the rules of the good manufacturing practice.

26. The members of the inspection team shall keep confidential the information obtained in the process of preparation and conduct of the inspection, as well as maintain the confidentiality of its results.

27. Inconsistency shall be regarded as the deviation of the quality system of the object of activity from the requirements of good pharmaceutical practices, identified during the inspection.

28. Inconsistency shall be divided into critical, significant and minor.

An inconsistency with the requirements of good pharmaceutical practice, causing or leading to a significant risk of the possibility of reducing the quality of the medicinal product, the production of the medicinal product in the course of its circulation, which is dangerous to human health and life shall be regarded as a critical inconsistency.

An inconsistency with the requirements of good pharmaceutical practice that is not classified as critical, causing or leading to a significant reduction in the quality of the medicinal product during its circulation, or a combination of inconsistencies, none of which is significant in itself, in the aggregate, representing a major inconsistency shall be regarded as a major inconsistency.

An inconsistency that does not fall into the category of critical or significant but is a violation of the requirements of the stated good pharmaceutical practice or inconsistency for

which there is not enough information to classify it as significant or critical shall be regarded as a minor inconsistency.

29. The inspection shall end with a final meeting with the responsible persons of the subject of inspection, at which the chief pharmaceutical inspector shall inform about the results of the inspection, listing all the discrepancies identified during the inspection.

30. If during the inspection critical inconsistencies with the requirements of the rules of good pharmaceutical practices are revealed, the inspection shall continue, and the chief pharmaceutical inspector shall send relevant information to the state body on the identified inconsistencies, based on which the state body shall make a decision, provided for in paragraph 2 of Article 259 of the Code, of which it shall notify in writing the subject of inspection, and also, if necessary, send it to law enforcement agencies and customs control authorities for taking relevant measures.

31. Based on the results of the inspection, the inspection team shall draw up a protocol of inconsistencies in the form in accordance with Annex 5 to these Rules, which indicates a brief description of the identified deviations.

32. The protocol of inconsistencies, drawn up in two copies, shall be signed by the inspection team and the head of the subject of inspection, one shall be transferred to the subject of inspection, 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 conduct of the pharmaceutical inspection (hereinafter referred to as the Inspection Report) in the form in accordance with Annex 6 to these Rules.

33. If critical deviations are identified, the subject of the inspection shall be recognized as not meeting the requirements of the declared good pharmaceutical practice.

34. The chief pharmaceutical inspector shall draw up an inspection report within the time limits established by the Quality Management of the Pharmaceutical Inspectorate, but no later than 30 calendar days from the date of completion of the inspection.

The report shall be drawn up in 3 copies and signed by the chief inspector and members of the inspection team.

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

35. If during the inspection inconsistencies were revealed, the subject of inspection shall, within the time limits established by the quality management of the pharmaceutical inspectorate, but no later than 30 calendar days from the date of receipt of the report, send a response to the pharmaceutical inspectorate with a corrective and preventive action plan and a report on its implementation, which the chief inspector and members of the inspection team become familiar with.

36. Within 15 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.

37. The results of the assessment shall be agreed upon within 5 calendar days with the pharmaceutical inspectorate of the state body.

38. One copy of the report on the results of the assessment shall be sent to the inspected subject (with a cover letter) no later than 10 calendar days from the date of its signing, the second copy shall be stored in the archive of the pharmaceutical inspectorate.

39. In the case of taking patterns (samples), the inspection report shall be drawn up after receiving the test results from the testing laboratory. In this case, the period specified in paragraph 34 of these Rules begins to be calculated from the day the state body, territorial subdivision or expert organization receives the test results.

40. Subject to the elimination of all inconsistencies, a certificate shall be issued.

The validity period of the certificate of compliance of the object with the requirements:

1) good manufacturing practice (GMP) shall be three years;

2) good distribution practice (GDP), good laboratory practice (GLP) - three years;

3) good pharmacy practice (GPP) - the first two times for five years, with subsequent confirmation - termless.

40-1. The issuance of a certificate for compliance with good manufacturing practice (GMP) shall be carried out without an inspection for manufacturers of medicines of the Republic of Kazakhstan licensed for pharmaceutical activities related to the production of medicines, based on an application and a letter of guarantee for the provision of documents in accordance with paragraph 12 of these Rules, submitted before July 1, 2021.

If the subject of inspection fails to apply in accordance with paragraph 12 of these Rules within six months from the date of issue of the certificate, the certificate issued in accordance with this paragraph shall be withdrawn.

Footnote. The rules supplemented by paragraph 40-1 in accordance with the order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.06.2021 No. ҚР DSM-56 (shall come into effect from the date of the first official publication).

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

1) non-elimination of identified inconsistencies based on the results of the assessment of the response with the application of a corrective and preventive action plan and a report on its implementation;

2) in case of failure to respond within the period established by paragraph 35 of these Rules;

3) in case of an obstacle in the implementation by the inspector of the inspection established in paragraph 25 of these Rules;

4) if the subject of inspection fails to ensure the conduct of the inspection by decision of the authorized body.

The subject of the inspection shall be sent a reasoned refusal to issue a certificate or conclusion.

42. Data on inspection subjects who have received a certificate shall be entered within three working days by a structural subdivision of a state body or its territorial subdivision into the Register of certificate holders for compliance with good pharmaceutical practices (hereinafter referred to as the Register of certificate holders) in the form in accordance with Annex 8 to these Rules for a period, corresponding to the validity period of the certificate.

Inspection documents shall be kept for five years.

43. In the event of a change in the name of the subject, a change in the name of the location address without physical relocation of the object, or inspection within a month, the subject of inspection shall notify the state body or its territorial subdivision in writing about this, attaching the relevant documents confirming the specified information. The state body or its territorial subdivision shall reissue the certificate or conclusion within ten working days.

44. If the certificate is lost, the subject of inspection shall receive its duplicate. The state body or its territorial subdivision within ten working days from the date of receipt of the application shall issue a duplicate.

45. The certificate holder shall inform

the pharmaceutical inspectorate of any planned changes in the organization that affect the information specified in the application and the validity of the certificate (change of name, address, change in volume, significant change in premises, equipment, operations).

Based on the nature of the changes, the Pharmaceutical Inspectorate shall decide to conduct a new inspection to verify compliance with the requirements of good pharmaceutical practices.

46. The state body or its territorial subdivision shall withdraw the certificate in the following cases:

1) at the request of the subject of inspection;

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

3) liquidation of the subject in the sphere of circulation of medicines, and medical devices ;

4) revealing critical inconsistencies based on the results of an investigation conducted based on applications from individuals and legal entities to a state body on the issue of the sale of low-quality products, inconsistency with the requirements of good pharmaceutical practices during transportation and storage of medicines;

5) failure to submit an application by the subject of inspection within a month after the end if a certificate was issued based on the results of a remote inspection;

6) in case of revealing critical inconsistencies during the inspection conducted at the manufacturers of medicines of the Republic of Kazakhstan that have a certificate for compliance with good manufacturing practice (GMP) without an inspection.

Footnote. Clause 46 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated June 30, 2021, No. ҚР ДСМ-56 (shall come into effect from the date of the first official publication).

47. The certificate shall cease to have an effect based on the withdrawal of the state body or its territorial subdivision.

The withdrawn certificate shall be subject to return to the state body or its territorial subdivision within five calendar days from the date of receipt by the subject of inspection of the notice of revocation of the certificate.

48. Information about certificates issued, suspended, or withdrawn by the state body or its territorial subdivision shall be entered in the register of certificate holders and posted on the Internet resource of the state body in the form in accordance with Annex 8 to these Rules.

Annex 1
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices
The form

For domestic applicants

To_____
name of the state body

Application for a pharmaceutical inspection of the facility

We hereby request you inspect

_____
indicate the target at the facility _____
at _____
Herewith, we declare:
Data of the subject of inspection:
Name of the legal entity/individual entrepreneur

_____
Legal address

_____
BIN/IIN _____
Address of the facility _____

_____

The license number for pharmaceutical activities and annexes to it (if any)

_____

Telephone/fax _____ _____
E-mail address _____
Last name, first name, patronymic (if any) position of the head

_____
Head _____
Last name, first name, patronymic (if any) signature
The authorized person of the subject of the inspection

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

Annex 2
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices
The form

For foreign applicants

To _____
name of the expert body

Application for a pharmaceutical inspection of the facility

We hereby request you to inspect of

_____
indicates the target at the facility _____
_____
at the address _____
___
Herewith, we declare:
Data of the subject of inspection:
Name of the legal entity/individual entrepreneur

_____
Legal address _____
___
Address of the facility _____
_____
No. of the license for pharmaceutical activities and annexes to it (if any)

_____
Phone/fax _____
E-mail address _____
____
Last name, first name, patronymic (if any) position of the head

_____

Head _____ _____

Surname, name, patronymic (if any) signature

The authorized person of the subject of the inspection

_____ _____

_____

Surname, name, patronymic (if any) signature

Annex 3
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices

List of medicinal products manufactured at the production site of the manufacturer or foreign manufacturer subject to inspection

Trade name of the medicinal product or name of the pharmaceutical substance	International non-proprietary name or grouping (chemical) name of the medicinal product or pharmaceutical substance	Dosage form, dosage (if any)	Marketing authorization, date of issue, expiry date or registry entry, date of inclusion in the API registry (if any)	Product type (indicated in accordance with Annex No. 3)

Compilation date "_____" _____ 20____

Head of the enterprise/authorized representative

(position) _____

Surname, name, patronymic (if any) signature

Annex 4
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices
The form

Pharmaceutical Inspection Program

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

_____

4. Date of inspection _____

_____

5. Name of the facility _____
6. Location of the facility _____
7. Composition of the inspection team and responsibility

No.		

	Surname, name, patronymic (if any) of pharmaceutical inspectors	Position, place of work
1.		

Each of the persons listed above who visits this establishment is responsible for the confidentiality of information that may become known to them during the inspection.

Inspection procedure

_____

8. Subject of inspection

_____

9. Prerequisites

_____

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

_____

10.Procedures _____

11. Inspection schedule

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

For remote GMP inspection

The list of documents submitted by the subject of inspection during a pharmaceutical inspection without visiting the inspection object

For remote GMP inspection

Requirements or justification	The last pharmaceutical inspection was carried out more than five years ago	The last pharmaceutical inspection was carried out 3 to 5 years ago
Description of GMP system and country regulations	Are national GMP requirements equivalent to RK or EAEU GMP requirements or GMP PIC/S guidelines?	Summary of changes made since the last inspection
Notarized copy of the production permit (license) issued by the national authorized body	Copy of license and changes made	Copies of the license and changes made since the date of the last inspection
Dossier of the production site (Site master file - SMF), compiled in accordance with the Standard of Good Manufacturing Practices of the Republic of Kazakhstan or the PIC/S guidelines	APD, complete or updated 6 months before the date of the pharmaceutical inspection. Information about planned changes	APD updated 12 months before the date of the pharmaceutical inspection . Information about planned changes
Schemes attached to the SMF. Schemes of pipelines and equipment	Colour diagrams of the water and air treatment system, diagrams of pipelines and equipment in A3 or A2 format	Colour updated diagrams in A3 or A2 format
List of manufactured medicines	Trade names and INN	Trade names and INN

Copy of the last inspection report with a notarized translation if necessary GMP certificates issued during these inspections	Report of the national authorized body issued within the last 2 years for the last 2 years (excluding entities located on the territory of the Republic of Kazakhstan), and if there is a PIC/S, WHO and FDA report(s)	The report of the national authorized body and the full report of the EU (except for entities located on the territory of the Republic of Kazakhstan). PIC/S, WHO and FDA report(s) issued within the last 3 years
Photos of the production site and auxiliary systems	External general view (from the air) Detailed view of the rooms, indicating the processes carried out in them (sampling, weighing, etc.)	External general view (from the air) Detailed view of the rooms, indicating the processes carried out in them (sampling, weighing, etc.)
Qualification master plan (premises and equipment)	List of premises, equipment and auxiliary systems used for production and their qualification status	List of all requalifications carried out since the last inspection
Validation master plan (production processes, cleaning and quality control)	List of processes used to manufacture/control the product and their validation status	List of all revalidations carried out since the last inspection
Report of external audits (if any)	Audit conclusions	Audit reports issued within the last 3 years
Dossier for a series of the product(s)	List of episodes released in the last 5 years A batch dossier containing the main part of the batch dossier and the analytical part	List of episodes released in the last 3 years A series dossier containing the analytical part
Handling complaints	The updated list of claims for all medicinal products manufactured at the production site	The updated list of claims for medicinal products (determined by the inspectorate) manufactured at the production site
Other*	Number of batches of all medicinal products rejected	Number of batches of all medicinal products rejected
Others (relative to the medicinal product/dosage form of interest)	Procedures for managing out-of-spec results Ongoing stability tests Data for all results that do not meet specifications and investigations* All process deviation reports (including remanufactured batches)*	Procedures for managing out-of-spec results Ongoing stability tests Data for all results that do not meet specifications and investigations* All process deviation reports (including remanufactured batches)*
Other	Letter of guarantee from the Authorized Person that the production site has been fully inspected for GMP requirements for the last 2 years, and that deviations have been eliminated	Letter of guarantee from the Authorized Person that the production site has been fully inspected for GMP requirements for the last 2 years, and that deviations have been eliminated
According to GMP requirements	Product quality overview	Product quality overview

Annex 5
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices
The form

Inconsistency protocol

Dated "__" _____ ____

Name of the subject of the inspection

_____

Object of activity _____

Deviations	Brief description of deviations	Note
Critical		
Essential		
Minor		

Head of inspection _____ _____

Surname, name, patronymic (if any) signature

Inspectors _____ _____

_

Surname, first name, patronymic (if any) signature

Head of the subject of inspection _____ _____

__

Surname, name, patronymic (if any) signature

Authorized person of the subject of inspection _____

_____ _____

Surname, name, patronymic (if any) signature

Annex 6
to the Rules for conducting
pharmaceutical inspections on
good pharmaceutical practices
The form

Pharmaceutical Inspection Report

Name of the pharmaceutical inspectorate

_____

address, phone, website

Name of the subject of inspection _____

Address_____

Foundation _____

___

1. Resume

Name of the inspected object	Name and full address of the object
License	
Company activities	
Date of inspection	

Information about inspectors (experts)	Surname, name, patronymic (if any), position
Inspection number (if any)	

2. Introduction

Brief description of the subject of inspection and the area being inspected.	
Date(s) of previous inspections	
Surname, name, patronymic (if any), the position of the inspectors who conducted the previous inspection	
Significant changes from the previous inspection	
Purpose of the inspection	
Inspected areas	
Personnel of the organization involved in the inspection	
Documents submitted by the subject of inspection before the inspection	

3. Observations and inspection results

For GMP inspections:

Quality control	
Staff	
Premises and equipment	
Documentation	
Production	
Quality control	
Outsourcing activities	
Complaints and product recalls	
Self-inspection	
Sales and transportation of products	
Evaluation of the dossier of the production site (if necessary)	
Miscellaneous	

For other inspections (GDP, GLP, GCP, GPP) - fill in the relevant sections of the rules of good pharmaceutical practice

4. List of deviations*

Critical	
Essential	
Other	

Note*

A critical deviation is an inconsistency with the requirements of good pharmaceutical practise, causing or leading to a significant risk of the possibility of reducing the quality of the medicinal product, the production of the medicinal product in the process of their circulation, which is dangerous to human health and life.

A major deviation is an inconsistency with the requirements of Good pharmaceutical Practice, which cannot be classified as critical causing or leading to a significant reduction in

the quality of the medicinal product during its circulation, or a combination of inconsistencies , none of which is significant in itself, but which together constitute a major inconsistency and must be explained and recorded as such.

Minor inconsistency - an inconsistency that does not fall under the category of critical or significant, but is a violation of established requirements (GxP rules), or a inconsistency for which there is not enough information to classify it as significant or critical.

5. Final meeting and assessment of the response of the subject of the inspection

Comments of representatives on the subject of inspection made during the final meeting	
Evaluation of the response of the subject of inspection on the identified comments	
Documents and/or samples taken during the inspection	

6. Inspection results and recommendations

Inspection results	
Recommendations	

The Pharmaceutical Inspection Report is drawn up and signed by:

Chief pharmaceutical inspector

_____

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

Members of the inspection team:

_____

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

_____

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

"_____" _____ _____

Sections 7 and 8 are completed by the inspection team after receiving information on eliminating deviations and agreeing with the pharmaceutical inspectorate of the state body

7. Results of the review of the elimination of deviations and the conclusions of the inspection

List of deviations	Deviation qualification	Information about the elimination of the deviation (summary of corrective and preventive actions, supporting document)	Deviation Elimination Evaluation

8. Conclusion

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

_____

Meets/does not meet the requirements of good pharmaceutical practice (insert name of good pharmaceutical practice)

Annex 7
to the Rules for conducting

pharmaceutical inspections
on good pharmaceutical practitioners
The form

Ministry of Healthcare of the Republic of Kazakhstan Medical and Pharmaceutical Control Committee

Certificate of compliance with the requirements of good pharmaceutical practices in the field of medicine circulation

No. _____
Date of issue "____" _____ ____
Valid until "____" _____ ___
Issued

_____
(full name, location, details of

_____
legal entity/individual entrepreneur)

_____
(name of the object)
Based on the information obtained during the pharmaceutical inspection,
the last of which was carried out and confirms compliance with good
pharmaceutical practice

_____
at the time of issuance
For production:
area of compliance with good pharmaceutical practice:
name of medicine groups

_____
stages of the technological process

_____
list of industrial premises, areas

_____
State authority issuing the certificate

_____
(full name) Head of the state body

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

Annex 8
to the Rules for conducting

pharmaceutical inspections
on good pharmaceutical practitioners

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

No.	Name, legal address, telephone number of the certificate holder	Certificate holder object address	Certificate number, date of issue, expiration date	Compliance area	Certificate Suspension and Revocation Information
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, No. 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 No. 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 No. 5942, published in 2010 in the Collection of Acts of Central Executive and Other central state bodies of the Republic of Kazakhstan No. 7).

2. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated November 6, 2014 No. 223 "On Amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 No. 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 No. 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 No. 396 "On amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 No. 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 No. 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 , No. KR DSM-26 "On amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 No. 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 No. 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 No. 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 No. 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 No. 5).

6. Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 16, 2019 , No. KR DSM-40 "On Amendments to the order of the Minister of Healthcare of the Republic of Kazakhstan dated November 19, 2009 No. 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 No. 18547, published on April 26, 2019, in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).