THE EURASIAN ECONOMIC COMMISSION'S COUNCIL

DECISION
No. 83 dated November 3, 2016

ON THE APPROVAL OF PHARMACEUTICAL INSPECTION RULES

as amended by the decisions of February 8, 2021 No 7, of August 19, 2020 No 127,
of June 23, 2020 No 66, of July 4, 2023 No 74 of the Council of the Eurasian Economic Commission

In accordance with Article 30 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Articles 7 and 10 of the Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union dated December 23, 2014, Paragraph 96 of Annex 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and Decision No. 108 of the Supreme Eurasian Economic Council "On Implementing the Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union" dated December 23, 2014, the Eurasian Economic Commission's Council has resolved as follows:

1. To approve the attached Pharmaceutical Inspection Rules.

2. This Decision shall enter into force after 10 calendar days have elapsed from the date of entry into force of the Protocol signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union dated December 23, 2014, but not earlier than 10 calendar days after the date of the official publication of this Decision.

Members of the Eurasian Economic Commission's Council:

For the Republic of Armenia	For the Republic of Belarus	For the Republic of Kazakhstan	For the Kyrgyz Republic	For the Russian Federation
V. GABRIELYAN	V. MATYUSCHEVSKY	A. MAMIN	O. PANKRATOV	I. SHUVALOV

APPROVED
by Decision No. 83
of the Eurasian Economic
Commission's Council
dated November 3, 2016

PHARMACEUTICAL INSPECTION RULES

I. General provisions

1. These Rules establish a unified procedure for the pharmaceutical inspectorate to conduct pharmaceutical inspections of the production of medicines for compliance with the Eurasian Economic Union's Good Manufacturing Practice approved by Decision No. 77 of the Eurasian Economic Commission's Council dated November 3, 2016 (hereinafter referred to as the inspection, the Good Manufacturing Practice).

2. To conduct the inspection, an inspection team shall be appointed, which includes the lead pharmaceutical inspector (hereinafter referred to as the lead inspector) and pharmaceutical inspectors. Third-party experts may be present during the inspection.

The requirements for the size of the inspection team, the level of qualification of the pharmaceutical inspectorate employees, and the experts involved in the work of the inspection team shall comply with the requirements established by the quality manual for the inspection of a corresponding type of pharmaceutical production site, as well as the General Requirements for the Quality System of Pharmaceutical Inspectorates of the Eurasian Economic Union Member States approved by Decision No. 82 of the Eurasian Economic Commission's Council dated November 3, 2016.

3. The pharmaceutical inspectorate shall guarantee confidentiality of information contained in the inspection documents.

4. The cost of inspections shall be financed by the inspected entity or its authorized representative.

II. Terms and definitions

5. For the purposes hereof, the concepts having the following meanings shall be used:

"applicant for a pharmaceutical inspection" means an inspected entity, a marketing authorization holder, an applicant for registration, or their authorized representative;

"inspection" means a pharmaceutical inspection phase which includes implementing activities by the inspection team in accordance with the inspection program;

"inspected entity" means a company engaged in the manufacturing of medicines and holding an authorization (license) for such activity issued by the authorized authority of the manufacturer’s country;

The concepts of "pharmaceutical inspection", "pharmaceutical inspectorate" and "pharmaceutical inspector" shall be used in their meanings defined in the General Requirements for the Quality System of Pharmaceutical Inspectorates of the Eurasian Economic Union Member States approved by Decision No. 82 of the Eurasian Economic Commission’s Council dated November 3, 2016.

III. Procedure

6. Inspections shall be performed by the pharmaceutical inspectorate according to the inspection plan (schedule) in accordance with the inspection program for medicine production sites set out in the form contained in Annex 1 (hereinafter referred to as the inspection program).

Inspection planning may be carried out in accordance with the risk management principles.

The following information shall be included in the inspection plan (schedule):

basis for inspection;

inspection dates;

inspected entity name;

inspected production site address (hereinafter referred to as the production site).

Inspections shall be performed on a scheduled and unscheduled basis.

The basis for inspection shall be a decision of the authorized authority in the field of pharmaceutical inspections of the Eurasian Economic Union Member State (hereinafter referred to as the authorized authority, the Member State, and the Union, respectively) and/or the application of the inspected entity (for example, for the purposes of licensing, registration, and implementation of the other registration procedures or investigations related to the quality of medicines).

7. Inspections may be conducted using the means of remote interaction (for example, using the means of audio or video communication) in special cases in accordance with Annex 2.

8. In order to organize an inspection, an applicant for a pharmaceutical inspection (hereinafter referred to as the applicant) shall provide for submission of the following documents to the pharmaceutical inspectorate in Russian and/or (if relevant requirements are contained in the legislation of the Member State) in the state language of the Member State (or translated into these languages):

for a corporate manufacturer (resident) located in the territory of a Member State:

an application for inspection;

a copy of a site master file in accordance with Part III of the Good Manufacturing Practice containing a copy of a manufacturing authorization (if any);

a list of medicines manufactured (to be manufactured) at the production site contained in Annex 3;

for a corporate manufacturer (non-resident):

an application for inspection;

a copy of a site master file in accordance with Part III of the Good Manufacturing Practice;

a duly certified copy or an electronic copy of a valid manufacturing authorization (license) issued by the authorized authority of a third country in the territory of which the production site is located or an extract from the relevant registry of a third country in the territory of which the inspected entity is located;

a duly certified copy of the document issued by the authorized authority (organization) of the country in the territory of which the medicinal products are manufactured, on the compliance of the production facilities (production site) with the good manufacturing practice applied in the country of manufacture (if any) or an electronic copy or an extract from the relevant registry of the country in the territory of which the inspected entity is located;

a list of medicines manufactured (to be manufactured) at the production site.

The application for inspection may be rejected in the following cases:

the information contained in the application for inspection or documents submitted at the request of the authorized authority (organization) is incomplete and/or unreliable;

the applicant fails to arrange the conditions for inspection, which prevents the inspection procedure;

the inspection costs are not paid by the due date (if applicable).

9. The inspection shall be conducted by the pharmaceutical inspectorate of the Member State in the territory of which the inspected site is located.

If the production site located outside the Union is inspected, the applicant shall be entitled to submit an application for inspection to the pharmaceutical inspectorate of one of the Member States.

In the event of a documented refusal of the pharmaceutical inspectorate of a Member State to conduct an inspection of a production site located in the territory of a third country, the applicant shall be entitled to submit an application for inspection to the authorized authority (organization) of another Member State.

The inspection initiated as part of the registration procedures shall be carried out by the pharmaceutical inspectorate of the Member State determined in accordance with the Rules for Registration and Examination of Medicines for Human Use approved by Decision No. 78 of the Eurasian Economic Commission's Council dated November 3, 2016.

10. The inspection procedure shall include the following steps:

acceptance and examination of submitted documents;

reaching agreement on the inspection dates with the inspected entity or its authorized representative;

formation of an inspection team;

drawing up and sending of the inspection program to the inspected entity or its authorized representative;

inspection of the production site, including the sampling of materials or products (if required) and their laboratory testing;

drawing up an inspection report (hereinafter referred to as the report);

evaluation (if required) of the corrective and preventive action plan, a report on its implementation, and evidence of remedial actions;

making a decision on issuing or refusing to issue a certificate of the manufacturer's compliance with the Eurasian Economic Union's Good Manufacturing Practice (hereinafter referred to as the certificate);

certificate issuance.

Time frames of individual inspection phases shall be established in accordance with the Member States' legislation with due regard to these Rules.

11. The inspection team shall be formed on the basis of a relevant disposition adopted by the head of the pharmaceutical inspectorate in accordance with the procedures established by the pharmaceutical inspectorate quality system.

The inspection team shall include at least two pharmaceutical inspectors.

12. The lead inspector and other members of the inspection team shall review documents, including the site master file, and other available information related to the purpose of the inspection, such as information about claims, quality defects, and product recalls (if any), obtained from public registers and databases or from other authorized authorities (organizations).

The lead inspector shall elaborate the inspection program using the form contained in Annex 1 hereto and prepare control sheets using the form contained in Annex 4, or other forms of working records provided for by the pharmaceutical inspectorate quality system. The inspection program shall be sent to the inspected entity at least 10 business days before the inspection start date.

The lead inspector shall allocate responsibilities in the inspection team and coordinate preparatory measures related to the inspection.

13. A kick-off meeting shall be held with representatives of the inspected entity at the beginning of inspection, at which the lead inspector shall introduce the inspection team members, get acquainted with the management and responsible persons of the inspected entity, announce the objectives and scope of inspection, clarify the inspection program and schedule, make a confidentiality statement, and answer questions of the inspected party.

The inspected entity shall determine the person responsible for assisting in the inspection.

14. The information received by the inspection team in the course of implementing the inspection program shall be recorded in control sheets or other forms of working records.

15. The contract (agreement) concluded by the pharmaceutical inspectorate and the inspected entity in respect of the inspection shall reflect (including, but not limited to), the following rights of the inspector:

to get access to (enter) any premise in accordance with the inspection program and the site master file;

to procure such evidence as documentation and photographic materials (video recordings) of premises and equipment;

to get access to any facility (item) and examine the same within the scope of inspection;

to take actions or require actions to be taken with respect to the items (tangible evidence) that may allegedly indicate non-compliance with the requirements of the Good Manufacturing Practice, including in terms of restricting access to these items and ensuring their safety for the purpose of further proceedings in the determined procedure;

to examine the inspected items, review the documentation and records, interview responsible persons of the inspected entity, and monitor activities at workplaces;

to terminate the inspection if the exercise of these rights is hindered.

The inspected entity shall also assume obligations, within the concluded contract (agreement), to ensure the possibility of performing actions provided for by the inspection program.

16. If any risk to the life and health of the population (including potential critical non-conformities) is identified, the lead inspector shall immediately inform the head of the pharmaceutical inspectorate (by phone, e-mail, or using other means of communication within 24 hours after the non-conformity is identified) and the chief executive officer of the inspected entity, and, if required, take

actions provided for by the quality system of the Members State's pharmaceutical inspectorate in accordance with Paragraph 28 hereof.

17. If so required, samples of materials or products may be selected during the inspection, which shall be sent by the inspected entity for testing to a testing laboratory determined in accordance with the Member State's legislation and having competence in accordance with the Member States' legislation. In this case, the cost of samples shall not be compensated.

The costs associated with the transportation, performance of customs operations, and customs control in respect of samples of materials and products transported across the customs border of the Union, as well as testing of samples shall be borne by the inspected entity. The selected samples of materials and products shall be imported into the customs territory of the Union in accordance with international treaties and acts included in the legislation of the Union governing the customs legal relations, and the legislation of the Member States on customs regulation.

18. At the end of each inspection day, the lead inspector shall hold a meeting with the inspection team members to discuss preliminary observations which, if required, shall be further discussed with the responsible persons of the inspected entity. In the case of any conflicts, the inspection team members shall answer questions asked by representatives of the inspected entity. If the non-conformities proposed to be classified as critical are identified, the lead inspector shall immediately inform the responsible persons of the inspected entity about the same.

The information provided by the responsible persons of the inspected entity on the elimination of identified non-conformities during the inspection shall be taken into account by the inspection team and shall be indicated in the report as non-conformities with a note about their elimination during the inspection.

At the final meeting with the responsible persons of the inspected entity, the preliminary findings of the inspection shall be announced and the identified non-conformities shall be discussed for the subsequent elaboration of a corrective and preventive action plan by the inspected entity, if required.

IV. Reporting procedure

19. The lead inspector shall arrange the preparation of a report in the form contained in Annex 5.

If no non-conformities are identified during the inspection, columns 1 to 4 of the table in Section 7 of Part II of the report shall specify "not applicable", a report shall be drawn up in 2 counterparts and signed by the lead inspector and members of the inspection team within 30 calendar days from the inspection completion date.

If only other non-conformities are identified, columns 5 and 7 of the table in Section 7 of Part II of the report shall specify "during the next inspection", a report shall be drawn up in 2 counterparts and signed by the lead inspector and members of the inspection team within 30 calendar days from the inspection completion date.

If critical and/or material non-conformities are identified during the inspection:

Part I of the report shall be made in 2 counterparts and signed by the lead inspector and the inspection team members within 30 calendar days from the inspection completion date;

Part II of the report shall be made in 2 counterparts and signed by the lead inspector and members of the inspection team within 30 calendar days after the inspected entity submits a corrective and preventive action plan and a report on its implementation (hereinafter referred to as the response) and documentary evidence of the elimination of all non-conformities in accordance with Paragraph 23 hereof or on the 61st calendar day after the inspected entity receives Part I of the report in the event that the inspected entity fails to submit a corrective and preventive action plan, a report on its implementation and data indicating the elimination of identified non-conformities within the period established by Paragraph 23 hereof.

If any samples of materials or products are taken, the term for compiling the report shall start to run from the date the lead inspector receives their testing results.

One copy of the report, Part I or Part II of the report, shall be sent to the inspected entity (under a cover letter) no later than 3 business days from the date of its signing, the second copy shall be deposited in the archives of the pharmaceutical inspectorate.

The pharmaceutical inspectorate shall submit a copy of the report to the authorized authority at its location.

Pharmaceutical inspectors shall be responsible for the accuracy of the inspection findings set out in the inspection report.

V. Further actions following the inspection

20. If other non-conformities are identified during the inspection, during the next inspection, the inspection team shall, including but not limited to:

evaluate the corrective and preventive action plan;

evaluate the report on its implementation.

21. The medicine production site shall be deemed compliant with the Good Manufacturing Practice in one of the following cases:

absence of non-conformities;

absence of critical and material non-conformities;

elimination of all critical and material non-conformities following the response evaluation.

22. The medicine production site shall be deemed non-compliant with the Good Manufacturing Practice in one of the following cases:

if critical and/or material non-conformities have been established in the report following the inspection;

if not all critical and material non-conformities have been eliminated following the response evaluation;

if no response is provided within the term prescribed by Paragraph 23 hereof;

if the inspector is prevented from exercising the rights established in Paragraph 15 hereof.

23. If critical and/or material non-conformities are identified during the inspection, the inspected entity shall, within 60 calendar days from the date of receipt of Part I of the report, send a response to the pharmaceutical inspectorate accompanied by a corrective and preventive action plan, a report on its implementation, as well as evidence of remedial actions.

24. The inspection team shall evaluate the information contained in the response and prepare Part II of the report in the manner provided for by Section IV hereof.

VI. Procedure for issuing, amending, suspending, renewing, and terminating the certificate

25. The authorized authority (organization) of the Member State shall ensure the issuance, amendment, suspension, renewal, and termination of the certificate following the inspection.

On the application submitted by the applicant accompanied by documents (copies thereof) confirming the need to make amendments not requiring the inspection (changing the name of the manufacturer's legal entity or name of the production site, the organizational and legal form of the manufacturer's legal entity, the address of the production site without changing its actual location; typo correction), amendments may be made to the certificate within 20 business days from the date of submitting the said application without sacrificing its number, date (period) of inspection and validity periods subject to inclusion of the relevant information into the databases of the Member States' authorized authorities (organizations), as well as the Union’s integrated information system.

26. If the medicine production site is deemed to comply with the Good Manufacturing Practice, the authorized authority (organization) shall issue a certificate in the form contained in Annex 6 (on the letterhead of the authorized authority (organization) of the Member State) within 10 business days from the date of the decision to issue the certificate in accordance with the legislation of the Member State.

The certificate shall reflect the status of the production site during the period of the inspection, apply to the dosage forms and manufacturing operations (manufacturing activities) specified therein, and is a document indicating the status of compliance. The validity period of the certificate cannot exceed 3 years from the inspection completion date. The certificate validity period may be shortened using the relevant risk management principles in accordance with the pharmaceutical inspectorate quality system if the certificate contains an appropriate entry thereof.

27. The basis for refusal to issue a certificate shall be recognition that the manufacturing operations are non-compliant with the Good Manufacturing Practice.

In the case of refusal to issue a certificate, the authorized authority (organization) shall notify the inspected entity in the manner prescribed by the legislation of the Member State, and within 10 business days from the date of the decision to refuse to issue a certificate.

28. If critical non-conformities with the Good Manufacturing Practice are identified during the inspection, the pharmaceutical inspectorate shall send a written notification of the identified non-conformities to the authorized authority (organization) of the Member State. The authorized authority (organization) of the Member State may decide to suspend or terminate the validity of a previously issued certificate whereof it shall notify the inspected entity and authorized authorities (organizations) of the other Member States and the Eurasian Economic Commission in writing within 5 business days from the inspection completion date.

29. The decision to renew the previously suspended certificate shall be adopted:

following the review of the corrective and preventive action plan, the report on its implementation, and evidence of remedial actions in accordance with the procedure specified in Paragraphs 23 and 24 hereof;

upon receipt of information following the review of the corrective and preventive action plan, the report on its implementation, and evidence of remedial actions from another authorized authority (organization) of the Member State.

30. The authorized authority (organization) of the Member State shall make a decision to terminate the validity of a previously issued certificate in the event of:

refusal of the inspected entity to pass the inspection at the request of the authorized authority (organization);

failure of the inspected entity to arrange the inspection at the request of the authorized authority (organization);

refusal by the authorized authority (organization) of the Member State, the pharmaceutical inspectorate of which carried out the inspection, or by the authorized authority (organization) of another Member State to issue a certificate.

31. If the inspected entity challenges the inspection findings, the pharmaceutical inspectorate shall consider complaints (appeals) in accordance with the procedure and within the terms established by the pharmaceutical inspectorate quality system and legislation of the Member States.

Complaints (appeals) against the decisions adopted by the pharmaceutical inspectorate shall be filed in accordance with the procedure established by the legislation of the Member States.

32. Information on issued certificates and certificates the validity of which has been suspended, renewed, or terminated and information on amendments in certificates shall be placed in the databases of the Member States' authorized authorities (organizations), as well as the Union’s integrated information system.

33. Pharmaceutical inspections using the means of remote interaction shall be conducted as provided in Annex 7.

Annex 1
to the Pharmaceutical Inspection Rules

(form)

PROGRAM
for Production Site Inspection

_____

(name of the enterprise and the inspected
production site,

_____

stages of production, quality control, dosage form)

for compliance with the Eurasian Economic Union's Good Manufacturing Practice

1. Basis for pharmaceutical inspection _____
2. Purposes of pharmaceutical inspection _____
3. Scope of pharmaceutical inspection _____
4. Date and place of inspection _____
5. Inspection team composition _____
6. Inspection facilities (in accordance with sections of the Eurasian Economic Union's Good Manufacturing Practice approved by Decision No. 77 of the Eurasian Economic Commission's Council dated November 3, 2016)

Part I. Main requirements	
1. Pharmaceutical quality system	
Quality guidelines	☐
Roles and responsibilities of the management	☐
Analysis by the management	☐
System of work with suppliers and contractors	☐
Change management system	☐
Deviation and non-compliance management system	☐
Corrective and preventive action system	☐
System for release of products into circulation	☐
Product quality reviews	☐
Quality risk management system	☐
2. Personnel	
Organizational structure	☐
Key personnel	☐
Training system	☐

Personnel hygiene	☐
Consultants	☐
3. Premises and equipment	
Design and qualification of premises, equipment, and utilities	☐
Monitoring, cleaning, and maintenance	☐
Warehousing, manufacturing, and auxiliary areas	☐
Quality control areas	☐
4. Documentation	
Documentation and records management	☐
Document storage	☐
Procedures and records	☐
5. Manufacturing	
Prevention of cross contamination	☐
Validation of cleaning processes and procedures	☐
Starting and packaging materials	☐
Process and in-process controls	☐
Packaging	☐
Manufacturing documentation and records	☐
Finished products: storage and sale	☐
Handling of non-compliant products	☐
6. Quality control	
Quality control system	☐
Quality control documentation	☐
Selection of samples	☐

Utensils, reagents, reference standards	☐
Testing	☐
Actions in regard to out-of-specification results	☐
Reference and retained samples	☐
Ongoing stability testing program	☐
Validation and transfer of test procedures	☐
7. Outsourced activities	☐
8. Claims, quality defects, and product recalls	☐
9. Self-inspection	☐
Part II. Basic requirements for drug substances used as starting materials	☐
Part III. Documents related to the Eurasian Economic Union's Good Manufacturing Practice	☐
Annex 1 – Requirements for Manufacturing of Sterile Medicines	☐
Annex 2 – Requirements for Manufacturing of Biological (Including Immunobiological) Drug Substances and Medicinal Products for Human Use	☐
Annex 3 – Requirements for Manufacturing of Radiopharmaceutical Medicines	☐
Annex 4 – Requirements for Manufacturing of Veterinary Medicines (Except for Immunobiological Veterinary Medicines)	☐
Annex 5 – Requirements for Manufacturing of Immunobiological Veterinary Medicines	☐
Annex 6 – Requirements for Manufacturing of Medical Gases	☐
Annex 7 – Requirements for Manufacturing of Herbal Medicinal Products	☐
Annex 8 – Requirements for the Selection of Samples of Starting and Packaging Materials	☐
Annex 9 – Requirements for Manufacturing of Liquid and Soft Dosage Forms	☐
Annex 10 – Requirements for Manufacturing of Pressurized Aerosol Metered-Dose Medicinal Products for Inhalation	☐
Annex 11 – Requirements for Computerized Systems	☐

Annex 12 – Requirements for the Use of Ionizing Radiation during the Manufacturing of Medicinal Products	☐
Annex 13 – Requirements for Medicinal Products for Clinical Trials	☐
Annex 14 – Requirements for Manufacturing of Medicinal Products Derived from Donated Blood or Plasma	☐
Annex 15 – Requirements for Qualification and Validation	☐
Annex 16 – Requirements for an Authorized Person's Confirmation of the Batch Compliance with the Purpose of Its Release	☐
Annex 17 – Requirements for Release by Parameters	☐
Annex 19 – Requirements for Reference and Retained Samples	☐

7. Inspection schedule

Date, Time <*>	Inspection Stage <**>	Full Name of the Inspector(s)
	1. Kick-off meeting	
	2. Quality system overview	
	3. Inspection of warehousing and manufacturing areas	
	4. Inspection of utilities and auxiliary areas	
	5. Inspection of quality control areas	
	6. Quality system documentation check	
	7. Audit of personnel training and hygiene documentation	
	8. Audit of manufacturing documentation	
	9. Audit of quality control documentation	
	10. Inspection team meeting	
	11. Closing meeting	

<*> The number of inspection days (duration) may vary depending on the medicine production site type and complexity.

<**> The approximate content of the inspection stages is given.

Signature of the inspector(s) who authored the program

Date of signing _____ __, 20

Annex 2
to the Pharmaceutical Inspection Rules

CASES
of Conducting Inspections Using the Means
of Remote Interaction (e.g. via Audio or Video Communication)

1. By decision of the pharmaceutical inspectorate, inspections may be conducted using the means of remote interaction (for example, via audio or video communication) in accordance with acts of the Eurasian Economic Union bodies in the following cases:

a) threat of emergence, actual emergence, and liquidation of an emergency and/or the emergence of a threat of:

outbreak of a disease posing a danger to other people;

diseases and injuries due to impact of adverse chemical, biological, and radiation hazards;

b) occurrence of the force majeure circumstances or circumstances beyond the parties' control, which pose a threat to the life and health of representatives of the expert organization (for example, for political, medical, or other reasons).

2. Before starting an inspection conducted using the means of remote interaction, the manufacturing organization shall confirm the geolocation data (latitude, longitude) of the production site.

Annex 3
to the Pharmaceutical Inspection Rules

LIST
of Medicines Manufactured (To Be Manufactured) at the Production Site
of the Inspected Entity

Brand Name of a Medicinal Product and/or Name of a Drug Substance	International Non-Proprietary Name or Grouping (Chemical) Name of a Medicinal Product and/or Drug Substance	Dosage Form, Strength (If Any)	Marketing Authorization, Date of Issue, Validity (Register Entry), Date of Inclusion in the Register for the Drug Substance (If Any)	Product Type (To Be Specified in Accordance with Annex 3 Hereto)

Annexes 1 and 2 shall form an integral part of the List of Medicines Manufactured at the Production Site of the Inspected Manufacturer or Foreign Manufacturer.

Date of compilation _____ __, 20____

Company's Chief Executive Officer (Authorized representative)			
(title)	(signature)	L.S.	(print name)

Annex 1
to the List of Medicines Manufactured
(To Be Manufactured) at the Production
Site of the Inspected Entity

LIST
of Manufacturing Operation Codes and Types of Imports
of Medicinal Products

Manufacturing and Quality Control (delete the inapplicable part)	
Code	Name
1. MANUFACTURING OPERATIONS — MEDICINAL PRODUCTS	
1.1	Sterile products
	1.1.1 Aseptically prepared products (processing operations for the following dosage forms):
	1.1.1.1 large-volume liquid dosage forms
	1.1.1.2 small-volume liquid dosage forms
	1.1.1.3 lyophilizates
	1.1.1.4 solid dosage forms and implants
	1.1.1.5 semi-solid dosage forms
	1.1.1.6 other aseptically prepared products _____ (please specify)
	1.1.2 Terminally sterilized (processing operations for the following dosage forms):
	1.1.2.1 large volume liquids
	1.1.2.2. small-volume liquid dosage forms
	1.1.2.3. solid dosage forms and implants
	1.1.2.4. semi-solid dosage forms
	1.1.2.5. other terminally sterilized products _____ (please specify)

	1.1.3 Batch release (batch certification)
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms):
	1.2.1.1 hard-shelled capsules
	1.2.1.2 soft-shelled capsules
	1.2.1.3 chewing dosage forms
	1.2.1.4 impregnated dosage forms
	1.2.1.5 liquid dosage forms for topical application
	1.2.1.6 liquid dosage forms for oral administration
	1.2.1.7 medicinal gases
	1.2.1.8 other solid dosage forms
	1.2.1.9 pressurized preparations
	1.2.1.10 radionuclide generators
	1.2.1.11 semi-solid dosage forms
	1.2.1.12 suppositories
	1.2.1.13 tablets
	1.2.1.14 transdermal patches
	1.2.1.15 other non-sterile products _____ (please specify)
	1.2.2 Release control (batch certification)
1.3	Biological medicinal products
	1.3.1 Biological medicinal products:
	1.3.1.1 blood products
	1.3.1.2 immunobiological products
	1.3.1.3 somatic cell products (somatic cell therapy products)
	1.3.1.4 gene therapy products
	1.3.1.5 biotechnology products
	1.3.1.6 products of human or animal origin
	1.3.1.7 tissue engineering products
	1.3.1.8 other biological medicinal products _____ (please specify)
	1.3.2 Release quality control (batch certification) (list of product types):
	1.3.2.1 blood products

	1.3.2.2 immunobiological products
	1.3.2.3 somatic cell products (somatic cell therapy products)
	1.3.2.4 gene therapy products
	1.3.2.5 biotechnology products
	1.3.2.6 products of human or animal origin
	1.3.2.7 tissue engineering products
	1.3.2.8 other biological medicinal products _____ (please specify)
1.4	Other medicinal products or manufacturing activities
	1.4.1 Manufacture of:
	1.4.1.1 plant products
	1.4.1.2 homoeopathic products
	1.4.1.3 other products _____ (please specify)
	1.4.2 Sterilization of active substances, excipients, and finished products:
	1.4.2.1 filtering
	1.4.2.2 dry heat sterilization
	1.4.2.3 steam sterilization
	1.4.2.4 chemical sterilization
	1.4.2.5 gamma sterilization
	1.4.2.6 electron beam sterilization
	1.4.3 Other _____ (please specify)
1.5	Packaging
	1.5.1 Primary packaging
	1.5.1.1 hard-shelled capsules
	1.5.1.2 soft-shelled capsules
	1.5.1.3 chewing dosage forms
	1.5.1.4 impregnated dosage forms
	1.5.1.5 liquid dosage forms for topical application
	1.5.1.6 liquid dosage forms for oral administration
	1.5.1.7 medicinal gases
	1.5.1.8 other solid dosage forms
	1.5.1.9 pressurized preparations

	1.5.1.10 radionuclide generators
	1.5.1.11 semi-solids
	1.5.1.12 suppositories
	1.5.1.13 tablets
	1.5.1.14 transdermal patches
	1.5.1.15 other non-sterile medicinal products _____ (please specify)
	1.5.2 Secondary packaging
1.6	Quality control
	1.6.1 Microbiological testing: sterility
	1.6.2 Microbiological testing: microbial limits
	1.6.3 Chemical (physical) testing
	1.6.4 Biological testing
2. Import of medicinal products	
2.1	Quality control testing of imported medicinal products
	2.1.1 Microbiological testing: sterility
	2.1.2 Microbiological testing: microbial limits
	2.1.3 Chemical (physical) testing
	2.1.4 Biological testing
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile products:
	2.2.1.1 aseptically prepared
	2.2.1.2 terminally sterilized
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products:
	2.2.3.1 blood products
	2.2.3.2 immunobiological products
	2.2.3.3 somatic cell products (somatic cell therapy products)
	2.2.3.4 gene therapy products
	2.2.3.5 biotechnology products
	2.2.3.6 products of human or animal origin
	2.2.3.7 tissue engineering products

	2.2.3.8 other biological medicinal products _____ (please specify)
2.3	Other import activities
	2.3.1 Physical import site
	2.3.2 Import of intermediate products which undergo further processing
	2.3.3 Other _____ (please specify)
3. MANUFACTURING OPERATIONS — DRUG SUBSTANCES Drug substance(s):	
3.1	Manufacture of drug substances by chemical synthesis method
	3.1.1 Manufacturing of drug substance intermediates
	3.1.2 Manufacture of crude drug substance
	3.1.3 Salification/purification: (please specify) _____ (e.g. recrystallization))
	3.1.4 Other _____ (please specify)
3.2	Manufacture of drug substances by extraction from natural sources
	3.2.1 Extraction of drug substances from plant sources
	3.2.2 Extraction of drug substances from animal sources
	3.2.3 Extraction of drug substances from human organs (tissues)
	3.2.4 Extraction of drug substances from mineral sources
	3.2.5 Modification of extracted drug substance (please specify the source from Paragraphs 3.2.1—3.2.4)
	3.2.6 Purification of extracted drug substance (please specify the source from Paragraphs 3.2.1—3.2.4)
	3.2.7 Other _____ (please specify)
3.3	Manufacture of drug substances using biological processes
	3.3.1 Fermentation
	3.3.2 Manufacturing using cell cultures _____ (please specify the type of cells used) (the type of cell cultures means their specificity, line, strain, etc.)
	3.3.3 Extraction (purification)
	3.3.4 Modification
	3.3.5 Other: _____ (please specify)
3.4	Manufacture of sterile drug substances (Sections 3.1, 3.2, and 3.3 shall be filled in, where applicable)
	3.4.1. Aseptically prepared drug substances

	3.4.2. Terminally sterilized drug substances
3.5	Final manufacturing stages of drug substances
	3.5.1 Physical processing stages (please specify) _____ (e.g. drying, grinding, sieving)
	3.5.2 Primary packaging
	3.5.3 Secondary packaging
	3.5.4 Other (for operations not described above) _____ (please specify)
3.6	Quality control
	3.6.1 Physical (chemical) testing
	3.6.2 Microbiological testing (including sterility testing)
	3.6.3 Microbiological testing (excluding sterility testing)
	3.6.4 Biological testing
4. OTHER OPERATIONS — DRUG SUBSTANCES (please specify)	

Company's Chief Executive Officer
(Authorized representative)

(title) (signature) L.S. (print name)

Annex 2
to the List of Medicines Manufactured
(To Be Manufactured) at the Production
Site of the Inspected Entity

LIST
of Medicines in Respect of Which the Inspection
Is Conducted

Brand Name of a Medicine	International Non-Proprietary Name or Grouping (Chemical) Name of a Medicinal Product and/or Drug Substance	Dosage Form, Strength (If Applicable)
All stages (including the batch certification)		
Manufacturing of finished dosage forms		
Primary packaging		

Brand Name of a Medicine	International Non-Proprietary Name or Grouping (Chemical) Name of a Medicinal Product and/or Drug Substance	Dosage Form, Strength (If Applicable)
Secondary packaging		
Quality control		
Batch certification		

Company's Chief Executive Officer (Authorized representative)

(title) (signature) L.S. (print name)

Annex 3
to the List of Medicines Manufactured
(To Be Manufactured) at the Production
Site of the Inspected Entity

LIST
of Types of Products Manufactured (To Be Manufactured)
at the Production Site of the Inspected Entity

Biological medicinal products:

blood products

immunological products

somatic cell products (somatic cell therapy products)

gene therapy products

biotechnology products

products of human or animal origin

tissue engineering products

other biological medicinal products (please specify the product type)

Other medicinal products:

plant products

homeopathic products

radiopharmaceutical medicines

cytostatic medicines

cytotoxic medicines

hormones

beta-lactam antibiotics

medicines containing superpotent substances

narcotic drugs

mind-altering medicines

other (please specify the product type)

List of types of active pharmaceutical ingredients:

drug substances manufactured by chemical synthesis

drug substances derived from plant sources

drug substances derived from animal sources

drug substances derived from biological sources

drug substances derived from mineral sources

drug substances manufactured by biotechnological synthesis

Annex 4
to the Pharmaceutical Inspection Rules

(form)

CHECKLIST

Paragraphs of the Eurasian Economic Union's Good Manufacturing Practice	Test Question	Object Identification	Information (Certificates) on Compliance	Information (Certificates) on Non-Compliance
1	2	3	4	5

Annex 5
to the Pharmaceutical Inspection Rules

(form)

INSPECTION
REPORT

_____
(name of the inspecting authority (inspecting organization))

_____
(name of the pharmaceutical inspectorate)

_____
(address, phone number, e-mail address, website address in the information and telecommunications network "Internet")

The organization of production and quality control of medicines has been inspected for compliance with the Eurasian Economic Union's Good Manufacturing Practice approved by Decision No. 77 of the Eurasian Economic Commission's Council dated November 3, 2016:

_____
(inspected entity name)

_____
(registered office of the inspected entity)

Basis (please underline as applicable):
application for pharmaceutical inspection (date, number)
decision of the authorized authority (date, number, and name of the authorized authority)
Form (please underline as applicable): with a visit to the site, using the means of remote interaction

Part I 1. General provisions		
1. Name of the inspected entity		
2. Location address(es) of the inspected production site		
3. Number and date of issue of the document issued by the authorized authority (authorized organization) of the country of manufacturing operations on compliance of the production facility (site) with the Good Manufacturing Practice applicable in the country of manufacture (if any), and/or the authorization (license) for such activity		
4. All types of the inspected entity’s activities	manufacture of drug substances	☐
	manufacture of medicinal products	☐
	intermediate products	☐
	bulk products	☐

	prepacking (primary packaging)	☐
	secondary packaging	☐
	import	☐
	contract manufacturing	☐
	quality control of medicinal products	☐
	batch release (batch certification)	☐
Other manufacturing activities	when filling in, specify, for example, sterilization of drug substances, excipients, finished products	
5. Kind (type) of medicinal products the manufacture of which has been inspected	sterile products	☐
	non-sterile products	☐
	biological medicinal products	☐
	plant products	☐
	homeopathic products	☐
	other products _____ (please specify)	☐
6. Date (period) of inspection		
7. Inspection team	lead inspector inspectors experts (if applicable) In the case of a joint inspection, also specify the authorized authority (organization) and the Eurasian Economic Union Member State they belong to	
8. Inspection number in accordance with the pharmaceutical inspectorate quality system (if any)		

2. Background information

1. Brief description of the inspected entity and production site	
2. Date (period) of the previous inspection <*>	
3. Inspection team which performed the previous	lead inspector

inspection	inspectors experts (if applicable) authorized authority (organization) of the Eurasian Economic Union Member State
4. Major changes since the previous inspection	when filling in, please specify GMP-critical changes
5. Objective and scope of inspection	when filling in, please specify whether manufacture of a specific medicinal product or dosage forms has been inspected
6. Inspected areas	list the areas to be inspected according to the inspection program
7. Personnel of the inspected entity involved in the inspection	please specify the full name and positions of the personnel
8. Documents submitted by the inspected entity prior to the inspection	

<*> In the case of repeated inspections in respect of this inspected entity, dates of all previous inspections shall be specified.

3. Comments and inspection findings

1. Pharmaceutical quality system (quality management for the active drug substance)	
2. Personnel	
3. Premises and equipment	
4. Documentation	
5. Manufacturing	
6. Quality control	
7. Outsourced activities	
8. Claims, quality defects, and product recalls	
9. Self-inspection	
10. Sale and transportation of products	
11. Evaluation of the site master file	
12. Issues considered in relation to the evaluation of the marketing authorization application	to be filled in if there is a request from an expert evaluating the marketing authorization application in accordance with the Rules of Registration and Examination of Medicines for Human Use approved by Decision No. 78 of the Eurasian Economic Commission's Council dated November 3, 2016
13. Other matters	When filling in, please specify, for example, the

	changes planned and previously reported by the company that are important for GMP
14. Selected samples (if applicable)	please specify the sampling certificate number

4. List of non-conformities

Seq. No.	Paragraphs of the Eurasian Economic Union's Good Manufacturing Practice	Detailed Description of the Identified Non-Conformity	Classification of Non-Conformities
1	2	3	4
			Critical <*>
			Material <**>
			Other <***>

<*> Non-conformities that cause or lead to a significant risk of manufacturing a medicinal product hazardous to human life and health.
<**> Non-conformities that cannot be classified as critical, but:
have led or may lead to the manufacture of a medicinal product non-conforming to the marketing authorization application for this medicinal product;
indicate a material deviation from the Eurasian Economic Union's Good Manufacturing Practice;
indicate a material deviation from the requirements of the other regulations in the field of medicines circulation;
indicate the inability of the inspected entity to carry out the serial
production of medicinal products of uniform quality or inability of the authorized person of the inspected entity to perform the official duties;
combination of non-conformities, none of which is material, but which together represent a material non-conformity and shall be explained and recorded by pharmaceutical inspectors as such.
<***> Non-conformities that cannot be classified as critical or material, but indicate a deviation from the Eurasian Economic Union's Good Manufacturing Practice.

5. Closing meeting and evaluation of the manufacturer's response

Comments of the inspected entity's representatives during the closing meeting	
Evaluation of the response on the identified non-conformities presented by the inspected entity during the closing meeting	
Documents submitted to the inspection team during the closing meeting	
Sampling results	please specify the number and date of the sample examination protocol

6. Inspection findings and recommendations

As a result of the inspection, non-conformities with the Eurasian Economic Union's Good Manufacturing Practice were identified as set out and classified in Part I of the Report.

Inspection findings	Total non-conformities: _____, including: critical <*> – ____;

	material <**> – ____; other <***> – ____. At the time of the inspection, the manufacturing of medicines _____ (name of the inspecting authority (inspecting organization)) conforms (does not conform) (please underline as applicable) with the Eurasian Economic Union's Good Manufacturing Practice
Recommendations	

The Inspection Report (Part I) has been executed and signed by:

Inspection team

	Full Name	Signature
Lead inspector		
Inspectors		
Experts (if applicable)		

, 20

_____

INSPECTION
REPORT

_____

(name of the inspecting authority (inspecting organization))

_____

(name of the pharmaceutical inspectorate)

_____

(address, phone number, e-mail address, website address in the information and telecommunications network "Internet")

Inspection of management of the medicines manufacturing process and quality control for conformity to the Eurasian Economic Union's Good Manufacturing Practice:

_____

(inspected entity name)

_____

(registered office of the inspected entity)

Basis (please underline as applicable):
application for pharmaceutical inspection (date, number)
decision of the authorized authority (date, number, and name of the authorized authority)

Part II 1. General provisions	
1. Name of the inspected entity	
2. Location address(es) of the inspected production site	

3. Time frame for evaluating the corrective and preventive action plan as well as the report on its implementation	
4. Inspection team	lead inspector inspectors experts (if applicable) In the case of a joint inspection, also specify the authorized authority (organization) and the Eurasian Economic Union Member State they belong to
5. Inspection number in accordance with the pharmaceutical inspectorate quality system (if any)	

7. Evaluation of the corrective and preventive action plan and the report on its implementation

Seq. No.	Paragraph of the Good Manufacturing Practice	List of Identified Non-Conformities	Non-Conformity Classification (Critical, Material, Other)	Evaluation of the Corrective and Preventive Action Plan	Information on Non-Conformity Elimination (Summary of a Remedial Action, Supporting Documents)	Evaluation of Non-Conformity Elimination
1	2	3	4	5	6	7

8. Conclusion

Following the evaluation of the corrective and preventive action plan and the report on its implementation, it is possible to adjust the classification and the number of identified non-conformities.

Seq. No.	Non-Conformity Number According to the Report	Non-Conformity Classification (Critical, Material, Other) in the Report	Classification of Non-Conformities with a Revised Status
1	2	3	4
1	1 <*>		the non-conformity status has not been changed <*>
2	5		the non-conformity status has been changed from "material" to "other"
3	6		eliminated

<*> In this form of the table, an example of filling in columns 2 and 4 is given.

Evaluation results	total non-conformities ____ including: critical <*> – ____; material <**> – ____; other <***> – ____.
Conclusion	The manufacture of medicines _____ (name of the inspecting authority (inspecting organization)) conforms (does not conform) (please underline as applicable) with the Eurasian Economic Union's Good Manufacturing Practice

The Inspection Report (Part II) has been executed and signed by:
Inspection team

	Full Name	Signature	Date
Lead inspector			
Inspectors			
Experts (if applicable)			

Annex 6
to the Pharmaceutical Inspection Rules

FORM
of the Certificate of Manufacture Conformity
to the Eurasian Economic Union's Good
Manufacturing Practice

THE EURASIAN ECONOMIC UNION

_____

(name of the authorized authority)

CERTIFICATE

OF CONFORMITY OF MEDICINES MANUFACTURE
TO THE EURASIAN ECONOMIC
UNION'S GOOD MANUFACTURING PRACTICE
No. GMP/EAEU/BY/000XX-20XX

(certificate reference number)

Valid from _____ to _____

Issued following a pharmaceutical inspection in accordance with the Pharmaceutical Inspection Rules approved by Decision No. 83 of the Eurasian Economic Commission's Council dated November 3, 2016

(full and abbreviated names of the authorized authority)

certifies the following:

the inspection has been conducted in respect of

(full name of the manufacturer)

(manufacturing site address)

based on (please specify one of the following):
Application No. _____ for a medicines manufacturing authorization (license);
plan for conducting pharmaceutical inspections of the holder of Medicines Manufacturing Authorization (License) No. __ _____;
Application No. _____ for the registration of medicines;

(another basis)

From the knowledge gained during the inspection, the latest of which was conducted on _____,
(date, period)

it has been established that this production site complies with the Eurasian Economic Union's Good Manufacturing Practice equivalent to the European Union Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use and the guidelines of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

This Certificate reflects the status of the production site at the time of the pharmaceutical inspection and shall not be relied upon to reflect the conformity status if more than 3 years have elapsed since the date of the most recent inspection. The certificate validity period may be shortened using the relevant risk management principles, if there is an appropriate entry thereof in the field "Restrictions or Explanatory Notes Regarding the Certificate Scope".

The Certificate shall only be valid if all pages (both main and additional sheets) are submitted.

The authenticity (veracity) of this Certificate may be checked in the database of

_____ .

(name of the authorized authority)

If the Certificate is not available in the specified database, please contact the issuing authorized authority.

_____

(form reference number)

(additional sheet)

☐ Medicines for human use

☐ Medicinal products for clinical research (testing)

Code	Name
1. MANUFACTURING OPERATIONS — MEDICINAL PRODUCTS	
1.1	Sterile products
	1.1.1 Aseptically prepared products (processing operations for the following dosage forms):
	1.1.1.1. Large-volume liquid dosage forms
	1.1.1.2. Small-volume liquid dosage forms
	1.1.1.3. Lyophilizates
	1.1.1.4. Solid dosage forms and implants
	1.1.1.5. Semi-solid dosage forms
	1.1.1.6. Other aseptically prepared products _____ (please specify)
	1.1.2. Terminally sterilized (processing operations for the following dosage forms):
	1.1.2.1. Large-volume liquid dosage forms
	1.1.2.2. Small-volume liquid dosage forms
	1.1.2.3. Solid dosage forms and implants
	1.1.2.4. Semi-solid dosage forms
	1.1.2.5. Other terminally sterilized products _____ (please specify)

	1.1.3. Batch certification (batch release)
1.2	Non-sterile products
	1.2.1. Non-sterile products (processing operations to prepare the following dosage forms):
	1.2.1.1. Hard-shelled capsules
	1.2.1.2. Soft-shelled capsules
	1.2.1.3. Chewing dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for topical application
	1.2.1.6. Liquid dosage forms for oral administration
	1.2.1.7. Medical gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressurized preparations
	1.2.1.10. Radionuclide generators
	1.2.1.11. Semi-solid dosage forms
	1.2.1.12. Suppositories
	1.2.1.13. Tablets
	1.2.1.14. Transdermal patches
	1.2.1.15. Other non-sterile products _____ (please specify)
	1.2.2. Batch release (batch certification)
1.3	Biological medicinal products
	1.3.1. Biological medicinal products:
	1.3.1.1. Blood products
	1.3.1.2. Immunobiological products
	1.3.1.3. Somatic cell products (somatic cell therapy products)
	1.3.1.4. Gene therapy products
	1.3.1.5. Biotechnology products
	1.3.1.6. Products of human or animal origin
	1.3.1.7. Tissue engineering products
	1.3.1.8. Other biological medicinal products _____ (please specify)
	1.3.2. Release control (batch certification) (list of product types):
	1.3.2.1. Blood products

	1.3.2.2. Immunobiological products
	1.3.2.3. Somatic cell products (somatic cell therapy products)
	1.3.2.4. Gene therapy products
	1.3.2.5. Biotechnology products
	1.3.2.6 products of human or animal origin
	1.3.2.7. Tissue engineering products
	1.3.2.8. Other biological medicinal products _____ (please specify)
1.4	Other medicinal products or manufacturing activities
	1.4.1. Manufacture:
	1.4.1.1. Plant products
	1.4.1.2. Homeopathic products
	1.4.1.3. Other products _____ (please specify)
	1.4.2. Sterilization of active substances, excipients, and finished products:
	1.4.2.1. Filtration
	1.4.2.2. Dry heat sterilization
	1.4.2.3. Steam sterilization
	1.4.2.4. Chemical sterilization
	1.4.2.5. Gamma sterilization
	1.4.2.6. Electron beam sterilization
	1.4.3. Other _____ (please specify)
1.5	Packaging
	1.5.1. Primary packaging:
	1.5.1.1. Hard-shelled capsules
	1.5.1.2. Soft-shelled capsules
	1.5.1.3. Chewing dosage forms
	1.5.1.4. Impregnated dosage forms
	1.5.1.5. Liquid dosage forms for topical application
	1.5.1.6. Liquid dosage forms for oral administration
	1.5.1.7. Medical gases
	1.5.1.8. Other solid dosage forms
	1.5.1.9. Pressurized preparations

	1.5.1.10. Radionuclide generators
	1.5.1.11. Semi-solid dosage forms
	1.5.1.12. Suppositories
	1.5.1.13. Tablets
	1.5.1.14. Transdermal patches
	1.5.1.15. Other non-sterile medicinal products _____ (please specify)
	1.5.2. Secondary packaging
1.6	Quality control
	1.6.1. Microbiological testing: sterility
	1.6.2. Microbiological testing: microbial limits
	1.6.3. Chemical (physical) testing
	1.6.4. Biological testing
For any restrictions or explanations related to these manufacturing operations (except in cases where such explanation is a general comment on the processes at the manufacturing facility), wherever the restrictions or explanations are applied, a reference to a relevant paragraph number of the GMP certificate shall be included.	
2. IMPORT OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.1. Microbiological testing: sterility
	2.1.2. Microbiological testing: microbial limits
	2.1.3. Chemical (physical) testing
	2.1.4. Biological testing
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile products:
	2.2.1.1. Aseptically prepared
	2.2.1.2. Terminally sterilized
	2.2.2. Non-sterile products
	2.2.3. Biological medicinal products:
	2.2.3.1. Blood products
	2.2.3.2. Immunobiological products
	2.2.3.3. Somatic cell products (somatic cell therapy products)
	2.2.3.4. Gene therapy products

	2.2.3.5. Biotechnology products
	2.2.3.6. Products of human or animal origin
	2.2.3.7. Tissue engineering products
	2.2.3.8. Other biological medicinal products _____ (please specify)
2.3	Other import activities
	2.3.1. Physical import site
	2.3.2. Import of intermediate products which undergo further processing
	2.3.3. Other _____ (please specify)
3. MANUFACTURING OPERATIONS — DRUG SUBSTANCES Drug substance(s):	
3.1	Manufacture of drug substances by chemical synthesis method
	3.1.1. Manufacturing of drug substance intermediates
	3.1.2. Manufacturing of crude drug substance
	3.1.3. Salification (purification): please specify (e.g., recrystallization)
	3.1.4. Other _____ (please specify)
3.2	Manufacture of drug substances by extraction from natural sources
	3.2.1. Extraction of drug substances from plant sources
	3.2.2. Extraction of drug substances from animal sources
	3.2.3. Extraction of drug substances from human organs (tissues)
	3.2.4. Extraction of drug substances from mineral sources
	3.2.5. Modification of extracted drug substance (please specify the source from Paragraphs 3.2.1—3.2.4)
	3.2.6. Purification of extracted drug substance (please specify the source from Paragraphs 3.2.1—3.2.4)
	3.2.7. Other _____ (please specify)
3.3	Manufacture of drug substances using biological processes
	3.3.1. Fermentation
	3.3.2. Manufacturing using cell cultures _____ (please specify the type of cells used) (the type of cell cultures means their specificity, line, strain, etc.)
	3.3.3. Extraction (purification)
	3.3.4. Modification
	3.3.5. Other _____ (please specify)

3.4	Manufacture of sterile drug substances (Sections 3.1, 3.2, and 3.3 shall be filled in, where applicable)
	3.4.1. Aseptically prepared drug substances
	3.4.2. Terminally sterilized drug substances
3.5	Final manufacturing stages of drug substances
	3.5.1. Physical processing stages (please specify) _____ (e.g. drying, grinding, sieving)
	3.5.2. Primary packaging
	3.5.3. Secondary packaging
	3.5.4. Other _____ (please specify for operations not described above)
3.6	Quality control
	3.6.1. Physical (chemical) testing
	3.6.2. Microbiological testing (including sterility testing)
	3.6.3. Microbiological testing (excluding sterility testing)
	3.6.4. Biological testing
4. OTHER OPERATIONS — DRUG SUBSTANCES _____ (please specify)	
Restrictions or explanatory notes regarding the certificate scope:	
(full name, title) (signature) (date of signing, DD/MM/YYYY) L.S. (form reference number)	

Any comments given in parentheses throughout the text shall not be reflected in the certificate and are given for reference only.

ANNEX 7
to the Pharmaceutical Inspection Rules

PROCEDURE
for Conducting Pharmaceutical Inspections
Using the Means of Remote Interaction

I. General provisions

1. The pharmaceutical inspection of medicines manufacture which provides for the use of the means of remote interaction (hereinafter referred to as inspection, remote inspection, respectively) shall be conducted in accordance with the Pharmaceutical Inspection Rules approved by Decision No. 83 of the Eurasian Economic Commission's Council dated November 3, 2016 (hereinafter referred to as the Rules), taking into account the specific features provided for hereby.

2. Remote inspection shall be conducted by pharmaceutical inspectors of the Eurasian Economic Union Member States' authorized authorities (organizations) by studying documents and materials, interviewing the representatives (employees) of the inspected entity using the means of remote interaction (e.g. via audio or video communication) and accessing information exchange systems without the visit of pharmaceutical inspectors to the production site.

II. Inspection planning

3. In addition to the provisions of the Rules, the inspected entity shall, prior to remote inspection, submit the documents and information according to the list specified in the Annex.

4. The pharmaceutical inspectorate shall make a decision to conduct remote inspection based on the evaluation of the risk criteria provided for by the quality system of this pharmaceutical inspectorate.

5. The documents and information specified in the list provided for in the Annex hereto shall be submitted by the applicant if the pharmaceutical inspectorate makes a decision to conduct remote inspection.

Submission of the above mentioned documents and information shall not be required if the applicant submits a letter stating that such documents (information) are included in the site master file and are relevant at the time of filing the application for inspection.

III. Provision with the means of remote interaction

6. The pharmaceutical inspectorate shall notify the inspected entity of remote inspection and of the need to organize technical testing of audio and/or video communication before the start of inspection.

7. Remote interaction using software and hardware, as well as their safety shall be ensured by the inspected entity in coordination with the pharmaceutical inspectorate.

8. In the event of unforeseen situations related to the provision of software and hardware for remote interaction, the parties shall during remote inspection immediately inform each other and take all possible measures to eliminate technical problems in the shortest possible time.

9. The pharmaceutical inspectorate quality system shall determine the rules for the interaction of pharmaceutical inspectors in case of remote inspection using various devices, as well as ways to provide all members of the inspection team with the necessary documents and information.

10. In order to assess the readiness of the inspected entity, the following should be taken into account:

a) possibility of using communication platforms for the timely provision of information, especially for the transfer of large-volume files;

b) possibility of holding an audio and/or video conference or using an alternative type of communication for the real-time discussion of issues related to remote inspection with the employees of the inspected entity;

c) possibility of joint use of technical devices for displaying the screens of computerized systems used by the inspected entity at the production site, or possibility of providing pharmaceutical inspectors with remote (read-only) access to computerized systems;

d) possibility of submission of video recordings from real-time surveillance cameras or video recordings for remote analysis of manufacturing operations, equipment, premises and related documentation (with specification of the time of video recording). Video conferences, as well as audio and/or video materials submitted by the inspected entity during remote inspection may not be re-recorded or recorded without the consent of the inspected entity;

e) time zones and geolocation data of the inspected entity and location of pharmaceutical inspectors;

f) organization by the inspected entity of the work of an interpreter throughout remote inspection or during a determined period, depending on the request of the pharmaceutical inspector(s).

IV. Preparation for an inspection

11. A remote inspection program (hereinafter referred to as the program) shall be drawn up, taking into account the evaluation of the risk criteria provided for by the pharmaceutical inspectorate quality system, and shall contain information that the inspection will be conducted without visiting the place of manufacturing activities.

12. Before the start of remote inspection, the inspected entity shall make available documents, materials and information under the program in electronic form (with translation into Russian or English) by placing them in a cloud storage or in any other way agreed with the pharmaceutical inspectorate.

V. Conduct of remote inspection

1. Kick-off meeting

13. Remote inspection shall begin with a kick-off meeting held via audio and/or video communication or an alternative mode of communication where:

a) the inspection schedule shall be reviewed and brief information shall be provided on the process of interaction between pharmaceutical inspectors and the inspected entity;

b) it shall be discussed that any video or audio recording of the inspection shall be agreed by the inspected entity and the pharmaceutical inspectorate;

c) the inspected entity shall confirm the geolocation data (latitude, longitude) of the inspected production site.

2. Remote inspection

14. At the end of each day of remote inspection, pharmaceutical inspectors shall draw up a list of questions and a list of necessary documentation provided for by the Eurasian Economic Union's Good Manufacturing Practice approved by Decision No. 77 of the Eurasian Economic Commission's Council dated November 3, 2016, and send them by e-mail to the inspected entity.

15. If necessary, an audio and/or video conference shall be held in coordination with the inspected entity to provide answers to questions.

3. Closing meeting

16. Remote inspection shall end with a closing meeting held via audio and/or video communication or an alternative mode of communication agreed with the inspected entity. At the closing meeting, the program implementation results shall be summed up and the inspection team shall announce the identified non-conformities to be discussed in detail with the inspected entity, a list of questions that remain unresolved, and a list of necessary documentation provided for by the Eurasian Economic Union's Good Manufacturing Practice to be submitted by the inspected entity within 5 business days from the end date of the inspection (from the date of the closing meeting) or within another period agreed by the inspected entity and the pharmaceutical inspectorate.

VI. Procedure following remote inspection

17. The lead inspector shall ensure that a report is drawn up in the form provided for in Annex 5 to the Rules (subject to Paragraph 19 of the Rules) with specification of information about remote inspection.

18. Based on inspection findings, the authorized authority (organization) of the Member State shall, in accordance with the procedure specified in the Rules, ensure the issuance of a certificate of conformity of medicines manufacture to the Eurasian Economic Union's Good Manufacturing Practice with specification of information about remote inspection.

19. After the removal of the restrictions imposed in the cases provided for in Annex 2 to the Rules, the conduct of pharmaceutical inspection with a visit to the place of manufacturing activities shall be ensured, subject to the validity period of the certificate specified in Paragraph 18 hereof. For production sites inspected for the first time, the pharmaceutical inspectorate shall conduct subsequent pharmaceutical inspection with a visit to the production site in case of detecting 1 or more critical non-conformities or more than 5 material non-conformities.

ANNEX
to the Procedure for Conducting Pharmaceutical Inspection
Using the Means of Remote Interaction

LIST
of Additional Documents and Information
To Be Submitted by the Inspected Entity prior to Inspection
Using the Means of Remote Interaction

1. Information characterizing the type of products (in addition to the list provided for in Annex 3 to the Pharmaceutical Inspection Rules approved by Decision No. 83 of the Eurasian Economic Commission's Council dated November 3, 2016) (e.g. orphan medicinal products, medicinal products included in special lists etc.).

2. Number of pharmaceutical inspections conducted in regard to the production site (total number of pharmaceutical inspections conducted by the pharmaceutical inspectorate of the state on whose territory the production site is located, and by the pharmaceutical inspectorates of other states, including the Eurasian Economic Union Member States (hereinafter referred to as the Member States)).

3. Frequency of production site inspection by the pharmaceutical inspectorate of the state on whose territory the production site is located (frequency of pharmaceutical inspections).

4. Number of pharmaceutical inspections conducted in regard to the production site by the pharmaceutical inspectorates of the Member States (total number of inspections; types of dosage forms).

5. Number of claims and recalls for 3 previous years (information posted on the official websites of the Member States' authorized authorities in the information and telecommunications network “Internet”; data kept in the file of the inspected entity and submitted by it in regard to a specific production site).

6. If the inspection is repeated – list of the most significant changes in the process at the production site for 3 previous years, including:

a) cases of organizing the manufacture of new types of products (e.g. antibiotics, cytotoxic medicinal products etc.);

b) changes that have affected the critical parameters of production process stages;

c) changes in engineering systems and parameters of product quality indicators.

7. List of critical and material deviations identified over 3 previous years and the control results of product batches (lots) that fail to conform to the acceptance criteria set out in the specifications (with a brief description for each of the listed events).

8. Corrective and preventive action plan (CAPA) which contains information on all planned and implemented corrective and preventive actions after pharmaceutical inspections conducted by the pharmaceutical inspectorates of the Member States over 3 previous years.

9. Information on the registration of new (for the Eurasian Economic Union's common market of medicines) medicinal products and their circulation in the markets of third countries (information shall be provided if the site produces a medicinal product not registered in the Member States, but already registered in third countries).