Receipt by the Ministry of Industry and Trade of the Russian Federation of an application and additional documents for the Certificate issuance

Application and set of documents registering

The Ministry of Industry and Trade of the Russian Federation within a period not exceeding 10 working days from the date of receipt of the application and documents shall check the accuracy of filling out the application, completeness of documents and reliability of information contained therein

Notification of the applicant of the need to eliminate deviations and (or) provide missing documents, within 3 working days since the inspection completion date

Elimination of deviations by applicant within 20 working days. Providing a complete and accurate set of documents

Refusal to conduct an inspection (in case requested documents were not provided in the period of 20 working days)

Notification of the applicant on the refusal of an inspection

The Ministry of Industry and Trade of the Russian Federation makes a decision (order) on conducting pharmaceutical inspection. Transfer of documents to the SID&GP (Authorized entity) within 5 working days

Adding the foreign manufacturer into the pharmaceutical inspections schedule. Posting information on the website of the Ministry of Industry and Trade of the Russian Federation

Sending a notification to the applicant by the Authorized agency on the periods of the inspection and the need to conclude an Agreement defining the procedure for inspection and the need to pay the costs of the Authorized entity

Refusal to conduct an inspection (in case of non-payment)

Forming of an inspection team

Forming an inspection plan, no later than 30 calendar days until the inspection beginning

Sending a plan of the inspection

Conducting an inspection no longer than 10 working days, not including travel time to the place of inspection. Sampling of materials or products (if necessary)

In the case of critical non-conformities identified in terms of the of Good Manufacturing Practice requirements, the Pharmaceutical Inspectorate sends the relevant information to the Authorized entity

Making an inspection report in 2 copies within 30 calendar days from the inspection completion date.
One copy of the report is sent to the inspected entity (with a cover letter) no later than 5 calendar days from the date of its signing, the second copy is stored in the archive of the Pharmaceutical Inspectorate. At the request of the Authorized entity, a copy of the report can be provided to it. In the case of sampling of materials or products, the report shall be prepared after receiving the tests results from the testing laboratory.

In case of non-conformities, the inspected entity, no later than 30 calendar days from the date of receipt of the report, sends a letter to the Pharmaceutical Inspectorate with an attachment of the CAPA plan and a report on its implementation

Within 30 calendar days of receipt of this letter, the Pharmaceutical Inspectorate evaluates the information contained therein.

The Ministry of Industry and Trade of the Russian Federation makes a decision to issue Certificate

The Ministry of Industry and Trade of the Russian Federation makes a decision to refuse the issuance of Certificate

Notification of the applicant on the issuance of Certificate

Notification of the applicant on the refusal to issue the Certificate within 3 working days after the Order approval

Posting information on issued, withdrawn certificates and certificates suspended or terminated on the website of the Ministry of Industry and Trade of the Russian Federation and in the Union's integrated information system, within 5 working days after the relevant decision