

**On approval of the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices**

***Unofficial translation***

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020 No. ҚР ДСМ-157/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 29, 2020 No. 21540

      Unofficial translation

      In accordance with paragraph 6 of Article 25 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and the health care system" **I HEREBY ORDER:**

      1. To approve the attached Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices.

      2. To declare as terminated:

      1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 412 "On approval of the Rules for the accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices" (registered in the State Register of Normative Legal Acts under No. 11487, published on July 14, 2015 in the Legal Information System “Adilet”);

      2) paragraph 5 of the List of some amended orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019 No. ҚР ДСМ-44 "On amendments to some orders of the Ministry of Healthcare Of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan" (registered in the State Register of Normative Legal Acts under No. 18582, published on May 2, 2019 in the Reference Control Bank of normative legal acts of the Republic).

      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) posting this Order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

      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 the 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 after the day of its first official publication.

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*Acting Minister of Healthcare* *of the Republic of Kazakhstan*
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*M. Shoranov*
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|   | Approved by Order of the ActingMinister of Healthcare of theRepublic of Kazakhstandated October 27, 2020No. ҚР ДСМ-157/2020 |

 **The Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices**

 **Chapter 1. General Provisions**

      1. These Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 6 of Article 25 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and health care system" (hereinafter referred to as the Code) and shall determine the procedure for accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of drugs and medical devices.

      2. In accordance with paragraph 6 of Article 25 of the Code, accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines, medical devices (hereinafter referred to as Accreditation) shall be carried out by a state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body).

      3. The following basic concepts shall be used in these Rules:

      1) accreditation - the procedure for the official recognition by the state body of the applicant's competence to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

      2) an accreditation certificate - an official document issued by a state body, confirming the competence of the entities of accreditation to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

      3) re-accreditation - the next procedure for the official recognition by the state body of the applicant's competence to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

      4) applicant - a testing laboratory carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices, having applied for accreditation.

 **Chapter 2. Procedure for accreditation**

      4. Accreditation shall be carried out within a period not exceeding forty working days from the date of receipt of the application, and include the following main stages:

      1) acceptance, consideration of the application and the submitted documents;

      2) examination of the applicant's facility at the location;

      3) deciding on accreditation or refusal of accreditation;

      4) issuance of an accreditation certificate.

      5. For accreditation, the applicant shall submit the following documents to the state body:

      1) an application for accreditation in the form in accordance with Annex 1 to these Rules, signed by the head of the applicant or a person authorized by him/her and certified by the seal of the organization;

      2) passport of the testing laboratory in the form in accordance with Annex 2 to these Rules, approved by the head of the applicant;

      3) quality manual in accordance with subparagraph 3-1) of paragraph 1 of Article 15 of the Law of the Republic of Kazakhstan dated July 5, 2008 "On Accreditation in the Field of Conformity Assessment" (hereinafter referred to as the Law).

      6. To consider the application and the submitted documents, as well as to conduct a survey of the applicant's facility at the location (hereinafter referred to as the Survey), the state body shall form an accreditation group of at least two people. The composition of the group shall be determined by the state body and include a head, a specialized specialist of the state body.

      The examination shall be carried out in the presence of representatives of the testing laboratory and the legal entity, which includes the testing laboratory.

      The examination period shall not exceed ten working days, calculated from the moment the accreditation team arrives at the applicant's location.

      7. Based on the results of the survey, the head of the group, taking into account all the comments of its members, shall draw up a report of the examination of the testing laboratory (hereinafter referred to as the Report) in the form in accordance with Annex 3 to these Rules in duplicate and signed by the members of the group.

      One copy of the report shall be provided to the applicant, the second copy shall be provided to the state body.

      8. The applicant, within twenty working days from the date of receipt of a notification (in any form) on the elimination of the revealed inconsistencies, shall eliminate the inconsistencies identified during the survey and notify the state body and the group of their elimination in writing with the submission of supporting documents.

      The accreditation team shall review the submitted documents within five working days.

      9. The state body, within five working days from the date of receipt of the group's report, shall decide to issue an accreditation certificate in the form in accordance with Annex 4 to these Rules or send a reasoned refusal to the applicant in writing (in any form).

      10. The accreditation certificate shall be issued for five years in accordance with paragraph 1 of Article 21 of the Law. After the expiration of the accreditation period, the testing laboratory is subject to re-accreditation.

      11. Re-accreditation shall be carried out in compliance with all the stages provided for in paragraph 5 of these Rules. The application for re-accreditation shall be submitted by the applicant no later than six months before the expiration of the accreditation certificate.

      12. During the validity of the accreditation certificate, the testing laboratory shall notify the state body of any changes affecting changes in the accreditation certificate, structural and qualitative changes associated with the activity.

      13. In case of changing the name of the subject of accreditation, changing the name of the location address without physically moving the object, within a month, the subject of accreditation notifies the state body in writing, with the attachment of the relevant documents confirming the specified information. The state body, within ten working days from the date of receipt of the application, shall re-issue the certificate.

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|   | Annex 1 to the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices |
|   | The form |

 **Application for accreditation**

      1. Name of the legal entity, organizational and legal form

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      hereby requests for accreditation of the testing laboratory for the implementation of monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices.

      2. Legal address of the organization (location, telephone, e-mail):

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      3. Surname, name, patronymic (if any) of the head of the legal entity

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      4. Last name, first name, patronymic (if any), telephone number of the employee responsible for communication with state accreditation body

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      5. The applicant is informed of the Rules for the accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices (hereinafter referred to as the Rules).

      Head \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

       (signature) (surname, initials)

      "\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_.

|  |  |
| --- | --- |
|   | Annex 2 to the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices |
|   | The form |
|   | Approved by\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Head of the organization,surname, initials, signature)"\_\_\_" \_\_\_\_\_\_\_\_\_\_ 20\_\_\_ |

 **Test laboratory passport**

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name of the legal entity)

       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (last name, first name, patronymic (if any), telephone number of the head of the testing laboratory)

       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (post address of the laboratory)

       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name, postal address of the legal entity that includes the testing laboratory)

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (phone, fax, email, test laboratory website)

      Table 1. Equipping the testing laboratory with test equipment (hereinafter referred to as TE)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|
Determined parameters of the tested products |
Name of TE, type, brand, manufacturer, serial and inventory numbers |
Main technical characteristics of the TE |
Commissioning year |
Date and number of the TE certification document, frequency |
Note |
|
1 |
2 |
3 |
4 |
5 |
6 |

      Table 2. Equipment with measuring instruments (hereinafter referred to as MI) for testing products in a testing laboratory

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|
Name of the determined characteristics (parameters) of the product |
MI name, type (brand), manufacturer, serial and inventory numbers |
Commissioning year, inventory number |
Metrological characteristics of MI |
Date, number of the certificate (certificate) of verification or attestation, frequency |
Additional information |
|
Measuring range |
Accuracy class, measurement errors |
|
1 |
2 |
3 |
4 |
5 |
6 |
7 |

      Note. A measuring instrument is a technical means intended for measurements, having normalized metrological characteristics, reproducing and (or) storing a unit of the physical quantity, the size of which is assumed to be unchanged (within the specified error) for a known time interval.

      Table 3. Condition of industrial premises of the laboratory (center)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|
Purpose of the premises (including types of tests performed) |
Area, m2 |
Temperature, С⁰ and humidity,% |
Illumination at workplaces, lx |
Gas level, mg/m3 |
Noise level dB |
Availability of special equipment (ventilation, anti-interference, etc.) |
Note |
|
1 |
2 |
3 |
4 |
5 |
6 |
7 |
8 |

      Note. The table is filled in based on the protocols for measuring the levels of production factors, carried out by specialists from the organizations of the sanitary and epidemiological service. The form is accompanied by a conclusion on the compliance of production facilities with sanitary and hygienic requirements, signed by the head of the organization of the sanitary and epidemiological service.

      Table 4. List of normative documents (hereinafter referred to as ND) used in testing

|  |  |  |
| --- | --- | --- |
|
ND designation |
ND name |
When and by whom it was approved, the number of the resolution (order) of the organization that approved the document, the date of introduction |
|
1 |
2 |
3 |

      Table 5. Information about the personnel performing tests for the examination and assessment of the safety of medicines and medical devices

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|
Surname, name, patronymic (if any) |
Position |
Education, diploma specialty, work experience in the specialty |
Types of tests carried out |
Date and number of the attestation protocol, frequency |
Note |
|
1 |
2 |
3 |
4 |
5 |
6 |

      Note: In the table, besides the employees of the testing laboratory, employees of other departments involved in the tests should be indicated (this is indicated in column 6).

      Head of the testing laboratory \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (signature) (surname, initials)

       "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_ 20\_\_\_

|  |  |
| --- | --- |
|   | Annex 3 to the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices |
|   | The form |

 **Testing laboratory survey report**

      1.Full name of the organization:

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      2. Legal address, phone, fax, e-mail:

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      3. Terms of the test: "\_\_\_\_" \_\_\_\_\_\_\_\_ 20\_\_\_ to "\_\_\_\_" \_\_\_\_\_\_ 20\_\_\_\_.

      4. Reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      5. The group consisting of the chairman

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (last name, first name, patronymic (if any), position, place of work) and a member of the group

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (last name, first name, patronymic (if any), position, place of work) held verification of

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name of organization) applying for accreditation for the right to carry out monopoly activities for the examination and assessment of the safety of drugs and medical devices.

      6. The test results:

|  |  |  |  |
| --- | --- | --- | --- |
|
No. |
Criteria for evaluation |
Description |
Remarks |
|
1 |
Information on the availability of constituent and legal documents |
 |
 |
|
2 |
Independence and confidentiality requirements |
 |
 |
|
3 |
Organization and management requirements |
 |
 |
|
4 |
Quality system requirements |
 |
 |
|
5 |
Personnel requirements |
 |
 |
|
6 |
Requirements for environmental conditions and premises |
 |
 |
|
7 |
Technical competence |
 |
 |
|
8 |
Documentation requirements |
 |
 |
|
9 |
Testing |
 |
 |
|
10 |
Requirements for handling test specimens |
 |
 |
|
11 |
Internal checks |
 |
 |
|
12 |
Working with contractors |
 |
 |
|
13 |
Handling complaints and appeals |
 |
 |
|
14 |
Information support requirements |
 |
 |

      7. List of discrepancies:

|  |  |  |  |
| --- | --- | --- | --- |
|
No. |
List of inconsistencies concerning the paragraphs of these Rules |
Nonconformity category |
Conclusions and solutions |
|
Critical |
Substantial |
Minor |
|
 |
 |
 |
 |
 |
 |

      8. Conclusions:

      The testing laboratory complies (not complies) with these Rules.

      Chairman of the Group \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (signature) (initials, surname) Group member: \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (signature) (initials, surname) Representatives of the testing laboratory: \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_

      (signature) (initials, surname) Acquainted with the report:

      Head of the organization \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (signature) (initials, surname) "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_

|  |  |
| --- | --- |
|   | Annex 4 to the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices |
|   | The form |

 **Accreditation certificate of a testing laboratory carrying out monopoly activities in the**
**examination and assessment of the safety and quality of medicines and medical devices**

      Date of issue "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_\_, Series, No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_

      This accreditation certificate was issued by the testing laboratory

      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      (name of organization, organizational and legal form, legal address)

       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

       that, by the decision of the state body, order No. \_\_\_\_\_ dated "\_\_\_" \_\_\_\_\_\_\_ 20\_\_ was accredited to carry out monopoly activities for the examination and assessment of safety and quality medicines and medical devices.

      The certificate is valid until "\_\_\_\_" \_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_\_

      Head of state body \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

      (surname, initials) (signature)

      Place of stamp

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