



On approval of the Rules for the issuance of a certificate for a pharmaceutical product (CPP)

Unofficial translation

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated January 21, 2021 No. ҚР ДСМ-8. Registered with the Ministry of Justice of the Republic of Kazakhstan on January 25, 2021 No. 22113

Unofficial translation

In accordance with clause 14 of Article 23 of the Code of the Republic of Kazakhstan dated July 7, 2020 “On Public Health and Healthcare System”, **I HEREBY ORDER:**

1. To approve the attached Rules for the issuance of a certificate for a pharmaceutical product (CPP).

2. To recognize as invalid:

1) order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 413 “On approval of the Rules for the issuance of a certificate for a pharmaceutical product (CPP)” (registered in the Register of State Registration of Regulatory Legal Acts under No. 11488, published on July 15, 2015 in “Adilet” Legal Information System);

2) order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated June 19, 2020 No. ҚР ДСМ-69/2020 “On amendments and additions to the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 413 “On approval of the Rules for the issuance of a certificate for a pharmaceutical product (CPP)” (registered in the Register of State Registration of Regulatory Legal Acts under No. 20879, published on June 22, 2020 in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan).

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 of information to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan on implementation of measures, set forth in subclauses 1) and 2) of this clause.

4. Control over execution of this order shall be entrusted to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall be enforced upon expiry of ten calendar days after the date of its first official publication.

*Acting Minister of Healthcare
of the Republic of Kazakhstan*

A. Giniyat
Approved by the order
of the Acting Minister of Healthcare
of the Republic of Kazakhstan
dated January 21, 2021 No.КР ДСМ-8

Rules for the issuance of a certificate for a pharmaceutical product (CPP)

Chapter 1. General provisions

1. These Rules for the issuance of a certificate for a pharmaceutical product (CPP) (hereinafter referred to as the Rules) have been developed in accordance with clause 14 of Article 23 of the Code of the Republic of Kazakhstan dated July 7, 2020 “On Public Health and Healthcare System” (hereinafter referred to as the Code), Article 14 of the Law of the Republic of Kazakhstan dated April 15, 2013 “On State Services” (hereinafter referred to as the Law) and shall determine the procedure for issuance of a certificate for a pharmaceutical product (CPP).

2. in these Rules, the following terms and definitions are used:

1) state body in the field of circulation of medicines and medical products – a state body exercising management in the field of circulation of medicines and medical products, control over the circulation of medicines and medical products.

2) certificate of conformity with the requirements of good manufacturing practice (GMP) – a document confirming the compliance of medicine manufacturing with the requirements of good manufacturing practice of the Republic of Kazakhstan;

3) holder of a registration certificate – developer, manufacturing organization, organization that has a document from the manufacturer for the right to own a registration certificate, responsible for the safety, quality and efficacy of the medicine (hereinafter referred to as the applicant);

4) certificate for a pharmaceutical product (CPP) – a document, which is issued by the authorized body in the field of healthcare for registration of domestic medicines abroad and for their export;

Chapter 2. Procedure for the issuance of a certificate for a pharmaceutical product (CPP)

3. A certificate for a pharmaceutical product (CPP) shall be issued for one name of a medicine with indication of one medicinal dose and for one importing country in Kazakh and Russian. Translation into other languages shall be carried out by the applicant.

A certificate for a pharmaceutical product (CPP) shall be issued for the period corresponding to the period of validity of the certificate of conformity with the requirements of good manufacturing practice (GMP), but no more than for three years.

4. To receive a certificate for a pharmaceutical product (CPP) the applicant shall submit to the Committee for medical and pharmaceutical control of the Ministry of Healthcare of the Republic of Kazakhstan (hereinafter referred to as the Committee) or through the web portal of “electronic government” www.egov.kz, www.elicense.kz (hereinafter referred to as the Portal), an application in the form according to Appendix 1 to these Rules, certified with electronic digital signature (hereinafter referred to as the EDS) and an electronic copy of the certificate of conformity with the requirements of good manufacturing practice (GMP) for the manufacturing site where the medicine is manufactured.

The list of basic requirements for the provision of a state service, including the characteristics of the process, form, content and result of the provision, is given in the standard of the state service "Issuance of a certificate for a pharmaceutical product" in accordance with Appendix 2 to these Rules.

The total period for reviewing documents and issuing a certificate for a pharmaceutical product shall be 5 (five) working days.

In case of emergency, in the context of the introduction of restrictive measures, including quarantine, the period for reviewing documents and issuing a certificate for a pharmaceutical product is up to 3 (three) working days.

When the service recipient submits all necessary documents:

through the portal in the "personal account" of the service recipient, the status of acceptance of the request for the provision of the state service shall be displayed, indicating the date of receipt of the result of the state service.

In cases of submission by the service recipient of an incomplete package of documents in accordance with the list, provided for in the Standard of State Service, the application shall be declined.

To the Portal:

If the applicant applies after the end of working hours, on weekends and holidays in accordance with labor legislation, the acceptance of applications and the issuance of the results of the provision of the state service shall be carried out on the next working day.

If the applicant submits an incomplete package of documents and (or) expired documents, an employee of the responsible structural unit of the Committee, within one working day from the date of receipt of the application, shall issue a reasoned refusal to further consider the application and (or) to provide the state service in the form in accordance with Appendix 3 to these Rules.

The Committee shall ensure entering the data on the stage of provision of state services into the information system for monitoring the provision of state services in accordance with

the procedure, set forth by the authorized body in the field of informatization according to subclause 11) of Article 5 of the Law on state services.

5. An employee of the responsible structural unit of the Committee within five working days prepares a certificate for a pharmaceutical product (CPP) (hereinafter referred to as the certificate) in the form according to Appendix 4 to these Rules, in case of manufacturing the medicine in the Republic of Kazakhstan only for export in accordance with subclause 5) of clause 2 of Article 23 of the Code – in the form according to Appendix 5 to these Rules, signed by the head and certified by the seal of the Committee, or provides a reasoned refusal to issue a certificate for a pharmaceutical product (CPP).

Issuance of the result of the provision of the state service to the applicant shall be carried out electronically through the Portal, or through the Office of the Committee.

6. The Committee shall maintain a register of issued certificates for pharmaceutical products (CPP).

7. Issuance of a duplicate of a certificate for a pharmaceutical product (CPP) (hereinafter referred to as the duplicate) shall be carried out by the Committee on the basis of a written application of the certificate holder (with an indication of the rationale for which purposes a duplicate is needed) within 5 (five) working days from the date of receipt of the application. A duplicate is issued for the duration of the original of a certificate for a pharmaceutical product (CPP).

The duplicate shall be stamped with “Duplicate” stamp.

8. The Committee shall refuse to issue a certificate for a pharmaceutical product (CPP) in cases as follows:

1) non-compliance of the manufacturing site (manufacture of the final product) with the requirements good manufacturing practice;

2) manufacture of the main medicine outside the territory of the Republic of Kazakhstan and the implementation of only the final packaging of the medicine in the territory of the Republic of Kazakhstan;

3) incomplete information in the application for the issuance of a certificate for a pharmaceutical product (CPP).

9. In case of changes in the information provided for in the certificate, the applicant shall submit the documents specified in clause 4 of these Rules to obtain a certificate.

The term and procedure for issuing a certificate shall be carried out in accordance with the procedure prescribed by Chapter 2 of these Rules.

10. A complaint against a decision, actions (inaction) of employees of the structural divisions of the service provider shall be filed in the name of the head of the service provider and (or) to the authorized body for assessment and monitoring the quality of state services in accordance with the procedure prescribed by the Law.

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

The complaint of the service recipient received by the authorized body for assessment and monitoring the quality of the provision of state services shall be subject to consideration within 15 (fifteen) working days from the date of its registration.

In cases of disagreement with the results of the decision of the service provider, the service recipient shall appeal the results through legal proceedings.

Appendix 1
to the Rules for the issuance
of a certificate for a pharmaceutical
product (CPP)

Form

Application for the issuance of a certificate for a pharmaceutical product (CPP)

_____,
(name of the applicant, with indication of the address and bank details) hereinafter referred to as the “Applicant”, represented by

(position, surname, name, patronymic (if any)) requests to issue a certificate for a pharmaceutical product
(CPP) for a medicine:

Trade name in exporting country	
Trade name in the importing country	
International non-proprietary name (if any)	
Dosage form, dosage, concentration, filling volume, number of doses in the package	
Name of domestic manufacturer	
Confirmation that the manufacturing site complies with the requirements of good manufacturing practice (GMP certificate number and validity period)	
Date of last inspection by the Committee	

A certificate for a pharmaceutical product (CPP) is intended for submission to _____

for the purposes of _____

(signature of the applicant) (surname, name, patronymic (if any))

Date


Appendix 2
to the Rules for the issuance
of a certificate for a pharmaceutical
product (CPP)

Standard of the state service “Issuance of the certificate for a pharmaceutical product”		
1	Name of service provider	Committee for medical and pharmaceutical control of the Ministry of Healthcare of the Republic of Kazakhstan.
2	Methods of provision of the state service	Acceptance of documents and issuance of the result of the provision of public services shall be carried out through: 1. Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan (hereinafter referred to as the service provider); 2. web portal of the “electronic government”: www.egov.kz (hereinafter referred to as the portal).
3	Period of provision of the state service	5 (five) working days. In case of emergency, under conditions of introduction of restrictive measures, including quarantine, the period for reviewing documents and issuing a certificate for a pharmaceutical product shall be up to 3 (three) working days.
4	Form of provision of the state service	Electronic (partially automatized) (paper)
5	Result of provision of the state service	Certificate for a pharmaceutical product or a reasoned refusal to issue a certificate for a pharmaceutical product (CPP). Issuance of the certificate shall be carried out in an electronic (paper) form.
6	The amount of payment charged to the service recipient for the provision of state services, and the methods of its collection in cases provided for by the legislation of the Republic of Kazakhstan	To legal entities, the state services shall be provided free of charge.
		1) of the service provider – from Monday to Friday in accordance with the established work schedule from 9.00 to 18.30, except for weekends and holidays according to

7	Work schedule	<p>the Labor Code of the Republic of Kazakhstan dated November 23, 2015 (hereinafter referred to as the Labor Code) with a lunch break from 13.00 to 14.30;</p> <p>2) the portal - around the clock, except for technical breaks in connection with the repair work (when the service recipient contacts after the end of working hours, on weekends and holidays in accordance with the Labor Code of the Republic of Kazakhstan, the application shall be accepted and the result of the provision of the state service shall be issued on the next working day).</p>
8	List of documents required for the provision of the state service	<p>Application for issuance of a certificate for a pharmaceutical product in the form according to Appendix 1 to these Rules;</p> <p>An electronic copy of the certificate of conformity with the requirements of good manufacturing practice (GMP) for the manufacturing site, at which the medicine is manufactured.</p>
9	Grounds for refusal to provide state services established by the legislation of the Republic of Kazakhstan	<p>1) establishing the unreliability of documents submitted by the service recipient for the receipt of a state service and (or) the data (information) contained in them;</p> <p>2) non-compliance of the service recipient and (or) the submitted materials, objects, data and information necessary for the provision of a state service with the requirements of these Rules;</p> <p>3) in relation to the service recipient, there is a court decision (verdict) that has entered into legal force on the prohibition of activities or certain types of activities requiring the receipt of a certain state service;</p> <p>4) in relation to the service recipient, there is a court decision that has entered into force, on the basis of which the service recipient is deprived of a special right, related to the receipt of a state service.</p>
		The Service Provider ensures that data on the stage of provision of public services is entered into the information system for monitoring

10	Other requirements, taking into account the specifics of the provision of state services, including those provided in electronic form and through the State Corporation	the provision of state services, in accordance with the procedure established authorized body in the field of informatization, according to subclause 11) of Article 5 of the Law on State Services. Contact numbers of inquiry services on the provision of state services: 8 (7172) 74-37-73, 74-22-27 Unified contact center for the provision of state services: 1414.
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Appendix 3
to the Rules for the issuance
of a certificate for a pharmaceutical
product (CPP)

[Name of the authorized body (in Kazakh)] Details of the authorized body in Kazakh		[Name of the authorized body (in Russian)] Details of the authorized body in Russian
Reasoned refusal in further consideration of the application and (or) in provision of a state service		
Number: [Number] Date of issue: [date of issue]	[Name of the applicant]	
[Name of the authorized body], having considered your application dated [date of application] No. [Number of the application], hereby informs _____ . [reason of refusal].		
[Position of the signatory]	[surname, name, patronymic (if any) of the signatory]	

Appendix 4
to the Rules for the issuance
of a certificate for a pharmaceutical
product (CPP)

A certificate for a pharmaceutical product (CPP)1 No. (Number of the certificate)

No.	Requirements	Information
1.1	Exporting country (country issuing the certificate)	
1.2	Importing country (requesting country)	
1.3	Trade name and dosage form of the medicine:	
	In the exporting country (if any)	
	In the importing country (if any)	
1.4	Name and amount of active substances per dose unit ³	

1.5	Information on the full composition, including excipients?	
1.6	Is the medicine registered for marketing in the exporting country ⁵ ?	
2	<p>Is the medicine actually marketed in the exporting country?</p> <p>If the answer to the question in clause 1.6 is “yes”, complete clauses 2.A and skip clauses 2.B</p> <p>If the answer to the question in clause 1.6 is “no”, skip clauses 2.A and complete clauses 2.B⁶</p> <p>Yes (no)</p>	
2.A.1	Registration certificate number ⁷	
2.A.2	(licenses) and date of issue	
2.A.3	Holder of registration certificate (license) (name and address)	
2.A.3.1	Marketing authorization holder status ⁸ (license) (according to the categories specified in note 8)	
2.A.4	<p>Is a brief justification for the decision to register¹⁰ attached?</p> <p>Yes (no)</p>	
2.A.5	<p>Is the information provided about the medicine approved, complete and consistent with the registration documents?¹¹</p> <p>Yes (no, not provided)</p>	
2.A.6	Applicant for a certificate if he/she is not a holder of a registration certificate for a medicine (license) (name and address) ¹²	
2.B.1	Applicant for the receipt of the certificate (name and address)	
2.B.2	Status of the applicant (according to the categories indicated in note 8)	
2.B.2.1	For category (B) and (C), the name and address of the manufacturer of the medicine ⁹	
2.B.3	Why is there no registration?	
2.B.4	not required (not requested, under consideration, declined)	
3	<p>Does the issuing body organize periodic inspections of the manufacturing site where the medicine is manufactured?¹⁴</p> <p>Yes (no, not applicable) (if “no” or “not applicable”, go to step 4)</p>	

3.1	Periodicity of scheduled inspections (years)	
3.2	Has the manufacturer of this type of dosage form been inspected? Yes (no)	
3.3	Does the manufacturing facility, equipment and manufacturing processes comply with GMP as recommended by the World Health Organization ¹⁵ Yes (no, not applicable)	
4.	Does the issuing authority recognize the information provided to be satisfactory in all aspects of the manufacture of the medicine? ¹⁶ Well no) (if no, give an explanation	

This certificate is issued by _____
(name and address of the body issuing

the certificate, telephone, fax)

(Surname, name, patronymic (if any) (signature) of the head of the body issued the certificate)

Date of issue “ _____ ” _____ 20 ____

Valid until “ _____ ” _____ 20 ____ Place for seal

Notes:

1. This certificate for a pharmaceutical product (CPP) (hereinafter referred to as the certificate) is made according to the format recommended by the World Health Organization and establishes the status of pharmaceutical product and the status of organization, applying for the certificate for a medicine in the exporting country.

2. Use international generic name or national generic names whenever possible.

3. The certificate or its appendix indicates the full qualitative composition of the finished medicine.

4. Detailed information on quantitative composition, but such information is provided only with the consent of the marketing authorization holder.

5. As an annex, detailed information is provided on any indications in the registration documents for the medicine, restrictions on sale, distribution or use, if any. If the answer is “yes”, go to clauses 2.A, clauses 2.B skip, if the answer is “no”, go to clauses 2.B and skip clauses 2.A.

6. Clauses 2.A and 2.B are mutually exclusive.

7. If the registration certificate is temporary or the medicine has not yet been registered, then this must be indicated.

8. Indicate the status of the holder of the registration certificate for the medicine:

A) is a manufacturer of a medicine and is responsible for quality and release into circulation;

B) carries out packaging, packaging and (or) labeling of the medicine, manufactured by another enterprise, at the same time is responsible for its quality and release into circulation;

C) does not participate in the manufacturing, packaging, packaging, but is responsible for its quality and release into circulation;

D) does not participate in any process.

9. Information is submitted only with the consent of the holder of the registration certificate, if the column is not filled in, this means that the marketing authorization holder has not given consent. Information about the place of manufacturing is a part of the registration certificate. In the event of a change in the place of manufacturing, appropriate changes shall be made to the registration certificate, otherwise it becomes invalid.

10. A brief justification is a document drawn up by an expert organization (the state expert organization in the field of circulation of medicines and medical devices is a state monopoly entity that carries out production and economic activities in the field of healthcare to ensure safety, effectiveness and quality of medicines and medical devices;) compiled on the basis of the results of an examination during state registration, re-registration, amendments to the registration dossier of the medicine, which served as the basis for the issuance of a registration certificate.

11. The information refers to the instructions for the medical use of the medicine approved by the Committee.

12. To issue a certificate, the applicant provides permission from the holder of the registration certificate of the medicine (license) to issue a certificate.

13. Specify the reason for not registering:

1) the medicine was developed exclusively for diseases not common in the country of export (for example, tropical diseases);

2) the composition of the medicine has been changed to improve its stability in tropical conditions;

3) the composition of the medicine has been changed to exclude excipients that are not approved for use in the country of import;

4) the composition of the medicine has been changed in order to meet other requirements regarding the maximum content of the active substance in the finished medicine:

1) the medicine has been developed exclusively for diseases that are not common in the country of export (for example, tropical diseases);

2) the composition of the medicine has been changed to improve its stability in tropical conditions;

3) the composition of the medicine has been changed in order to exclude excipients that are not approved for use in the country of import;

4) the composition of the medicine has been changed in order to meet other requirements regarding the maximum content of the active substance in the finished medicine;

5) other reasons with explanations.

14. "Not applicable" means that the medicine is not manufactured in the country where the certificate is issued for it, therefore, the inspection is carried out under the control of the authorities of the country of manufacture.

15. The requirements for appropriate manufacturing and quality control practices for the medicine specified in the certificate are in accordance with those included in Report 32 of the Committee of Experts on Certification of Medicines (WHO Technical Report Series No. 823, 1992, Appendix 1). The WHO Committee on Biological Standardization was formulated specific recommendations for biological standardization (WHO Technical Report Series No. 822, 1992, Annex 1).

16. The clause shall be filled in if the applicant corresponds to the status (B) or (C), which are indicated in clause 8 of the note. In such a case, the applicant shall provide the issuing body with information on which parties to the contract are responsible for each stage of the manufacturing process of the final product, as well as on the scope and nature of any types of quality control, conducted by each of these enterprises.

Appendix 5
to the Rules for the issuance
of a certificate for a pharmaceutical
product (CPP)

Form

A certificate for a pharmaceutical product (CPP) No. _____

No.	Requirements	Information
1.1	Exporting country (country issuing the certificate)	
1.2	Importing country (requesting country)	
1.3	International non-proprietary name and dosage form of the medicine:	
	In the exporting country	
1.4	Name and amount of active substances per dose unit 3	
1.5	Information on the full composition, including excipients?	
2.	Certificate applicant (name and address)	

2.1.	Status of the applicant (according to the categories indicated in the note) 8	
2.2.	For category (B) and (C), the name and address of the manufacturer of the medicine 9	
3	Does the issuing body organize periodic inspections of the production site where the medicine is manufactured? 14 Yes (no, not applicable) (if “no” or “not applicable”, go to step 4)	
3.1	Periodicity of scheduled inspections (years)	
3.2	Has the manufacturer of this type of dosage form been inspected? Well no)	
3.3	Does the facility, equipment and manufacturing processes comply with GMP as recommended by the World Health Organization 15 Yes (no, not applicable)	
4.	Does the authority issuing the certificate recognize the information provided as satisfactory in all aspects of the manufacture of the medicine? 16 Yes (no) (if no, explain)	

This certificate is issued for a medicine manufactured in the Republic of Kazakhstan only for export, not subject to state registration and sale in the Republic of Kazakhstan

(name and address of the body issued the certificate, telephone, fax)

(Surname, name, patronymic (if any) of the head (signature) of the state body (or the authorized person)

Date of issue “ _____ ” _____ 20 ____
Valid until “ _____ ” _____ 20 ____

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