On approval of the rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products, licensed to manufacture medicines and medical products

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 20, 2020 No. ҚР ДСМ -286/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21840.

Unofficial translation

In accordance with Article 232 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" **I HEREBY ORDER**:

Footnote. The preamble as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 97 (shall be enforced upon expiry of ten calendar days after its first official publication).

1. To approve the attached rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products.

2. To recognize as invalid the order of the Minister of Health of the Republic of Kazakhstan dated April 22, 2019 № ҚР ДСМ-45 "On approval of the Rules for manufacture of medicines and medical products" (registered in the Register of state registration of regulatory legal acts under № 18581, published on May 2, 2019 in Reference Control Bank of regulatory legal acts of the Republic of Kazakhstan).

3. The Committee for Control of Quality and Safety of Goods and Services of the Ministry of Health of the Republic of Kazakhstan, in the manner prescribed by the legislation of the Republic of Kazakhstan, to ensure:

1) state registration of this order in the Ministry of Justice of the Republic of Kazakhstan;

2) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order in the Ministry of Justice of the Republic of Kazakhstan, submission of information to the Legal Department of the Ministry of Health of the Republic of Kazakhstan on implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph.

4. The supervising vice minister of health of the Republic of Kazakhstan is authorized to control the execution of this order.

5. This order comes into force upon the expiration of ten calendar days after the day of its first official publication.

Minister of health of the Republic of Kazakhstan *A. Tsoi*

Approved
by the order
Minister of health of the
Republic of Kazakhstan
dated December 20, 2020
№ ҚР ДСМ-286/2020

Rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products

Chapter 1. General provisions

1. These Rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products (hereinafter - the Rules) determine the procedure for manufacture of medicines and medical products.

2. The manufacture of medicines and medical products is carried out by entities in the field of circulation of medicines and medical products, which have an appropriate license to manufacture medicines and medical products.

3. The following concepts are used in these Rules:

1) cross contamination - contamination of a source material, intermediate product or final product with another source material or product during production or storage;

2) manufacturing of medicines - pharmaceutical activities related to the manufacture of medicines in pharmacies, with the purchase of pharmaceutical substances (active pharmaceutical ingredients) for pharmaceutical use, storage, quality control, registration and sale of manufactured medicines;

3) manufacture of medical products - pharmaceutical activities related to the manufacture of medical products in pharmacies, stores of medical products and optical stores;

4) sterile medicines – drugs in a certain dosage form that have passed the sterilization process for the absence of living organisms;

5) good manufacturing practice - a national standard in the field of circulation of medicines and medical products, which establishes requirements for the organization of production, production process and control in manufacture of medicines and medical products

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4. Manufacturing of medicines shall be carried out on the basis of medicines registered in the Republic of Kazakhstan, except for medicinal substances produced under conditions of good manufacturing practice.

Footnote. Paragraph 4 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 97 (shall be enforced upon expiry of ten calendar days after its first official publication).

5. The technology for the manufacture of medicines and medical products manufactured in a pharmacy, a store of medical products and an optics store is carried out in accordance with the requirements of the general articles of the State Pharmacopoeia of the Republic of Kazakhstan, individual pharmacopoeial articles, foreign pharmacopoeias recognized as valid in the territory of the Republic of Kazakhstan, regulatory documents on quality of the drug.

6. In medical organizations that do not have a pharmacy with the right to manufacture medicines, it is not allowed to manufacture and (or) pack medicines, transfer medicines from one package to another, replace labels.

Chapter 2. Procedure for manufacture of medicines

7. Medicines are manufactured taking into account the following conditions:

1) compliance with the order of the Minister of Healthcare of the Republic of Kazakhstan dated October 2, 2020 № ҚР ДСМ-112/2020 "On approval of the Rules or prescribing, recording and storing prescriptions" (registered in the Register of State Registration of Regulatory Legal Acts under № 21493), compliance of prescribed doses with the patient's age , norms of one-time dispensing, compatibility of ingredients included in the composition of the medicinal product;

2) compliance with the manufacturing technology of the medicines;

3) provision of the medicine with appropriate labeling and packaging;

4) ensuring the proper release of the medicine with the provision of objective information to the patient about the medicines in accessible terms for their use and storage.

Footnote. Paragraph 7 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 02.06.2023 № 97 (shall be enforced upon expiry of ten calendar days after its first official publication).

8. Manufacturing of medicines is carried out:

1) according to prescriptions of doctors;

2) according to the requirements of medical organizations;

3) in the form of an intra-pharmaceutical preparation.

9. In the manufacture of medicines, deviations are allowed, within the limits of the norms permissible for the manufacture of medicines (including homeopathic ones) in the pharmacy, the permissible error in measuring the acid-base balance in accordance with Appendices 1, 2 to these Rules.

10. The conditions for sterilization, storage and shelf life of medicines manufactured in the pharmacy are established in accordance with Appendix 3 to these Rules.

11. Medicines from a pharmacy are released to medical organizations only to authorized medical personnel under a power of attorney drawn up in the manner prescribed by the Civil Code of the Republic of Kazakhstan dated December 27, 1994.

12. Sterile medicines are manufactured under aseptic conditions, such as:

1) medicines for newborns;

2) solutions for injections and infusions;

3) irrigation solutions introduced into cavities that do not contain microorganisms;

4) liquid medicines for newborns and children under one year old;

5) preparations in the form of a liquid dosage form containing antibiotics and other antimicrobial substances, as well as those intended for application to wounds and burn surfaces;

6) eye drops, ophthalmic solutions for irrigation and lotions;

7) concentrated solutions (including homeopathic dilutions);

8) liquid medicines in the form of an intra-pharmaceutical preparation.

13. The manufacture of sterile medicines is carried out if there is data on the chemical compatibility of the medicinal substances included in them, technology and sterilization mode .

14. Simultaneous production of several sterile solutions containing medicinal substances with different names or of the same name, but in different concentrations, is not carried out at one workplace.

15. The results of the control of individual stages of the manufacture of solutions for injections and infusions are recorded in the register of the results of control of individual stages of the manufacture of solutions for injections and infusions according to the attached form in accordance with Appendix 4 to these Rules.

The register is numbered, laced up, certified by the signature of the head of the pharmacy.

16. Control of sterile solutions for the absence of particulate matters is carried out before and after sterilization.

In pharmacies, the volume of solutions in vials (bottles) and the quality of their closure are checked. When checking manually, if the solution is poured out when the vial (bottle) is overturned, the metal cap must not be rotated "running-in").

17. Bottles with solutions after capping are marked by writing and stamping on the lid.

18. Sterilization of solutions is carried out no later than three hours from the beginning of manufacture, under the supervision of a specialist (pharmacist or senior pharmacist).

Re-sterilization of solutions is not performed.

The sterilization parameters are registered in the register of the sterilization regime of the source medicinal substances, manufactured medicines, auxiliary materials, tableware in the form in accordance with Appendix 5 to these Rules.

The register is numbered, laced up, certified by the signature of the head of the pharmacy.

Chapter 3. Procedure for manufacture of medical products

19. Medical products are manufactured subject to the following conditions:

1) when used for their intended purpose (during operation) in accordance with the instructions and information provided by the manufacturer of the products, safety is ensured and the health of patients and users is not endangered;

2) their characteristics are preserved during storage and transportation;

3) excludes or minimizes the risk of infection of patients, users, as well as cross-contamination of the products themselves.

20. Technical characteristics and functional properties of medical products do not deteriorate during the service life of a medical product specified by the manufacturer, under the influence of external factors, and do not endanger the health and safety of patients, users during normal operation of the product under conditions that comply with the manufacturer's instructions for use.

21. Medical products intended for the administration of medicines are compatible with these medicines taking into account the functional properties of medical products in accordance with their intended purpose, the conditions of use and storage of these medicinal products.

22. Manufacturing of medical optics is carried out on machines specially designed for processing of optical lenses in accordance with a prescription written for a particular patient.

23. It is mandatory to check the accuracy of the glasses made using special equipment (diopter) in the presence of the client, for compliance with the prescription data.

Appendix 1
to the Rules for manufacture of
medicines and medical products by
entities in the field of circulation of
medicines and medical products
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Form

Norms of deviations permissible in the manufacture of medicines (including homeopathic ones) in a pharmacy

1. Deviations permissible in the mass of individual doses when filling powders, including powder dispensers, are determined for the prescribed dose of one powder.

Deviations permissible in the total mass of homeopathic triturations are determined by the prescribed mass of triturations

prescribed mass, gr	Deviations %
1	2
Up to 0,1	±15
over 0,1 to 0,3	±10
over 0,3 to 1	±5
over 1 to 10	±3
over 10 to 100	±3
over 100 to 250	±2
over 250	±0,3

2. Deviations permissible in the total mass of homeopathic granules (including when packing) per package:

prescribed mass, gr	Deviations %
1	2
Up to 1	±5
over 1 to 100	±3

3. Deviations permissible in the mass of individual doses of suppositories and pills:

1) determine the average weight by weighing (accurate to 0.01 g) at least 10 suppositories or pills. When making less than 10 pieces, all suppositories are weighed;

2) deviations in the mass of suppositories and pills from the average mass are determined by weighing each suppository or pill with a minimum sampling of 5 pieces;

3) it is not allowed to exceed the permissible deviations from the average weight:

for suppositories ± 5%;

for pills weighing up to 0.3 g ± 10%;

for pills weighing more than 0.3 g ± 5%.

4. Deviations permissible in the mass of prescribed doses of individual medicinal substances in powders, pills and suppositories (when manufactured by rolling out or pouring out) are determined for the dose of each substance included in these medicines:

prescribed mass, gr	Deviations %
1	2
Up to 0,02	±20
over 0,02 to 0,05	±15
over 0,05 to 0,2	±10
over 0,2 to 0,3	±8
over 0,3 to 0,5	±6
over 0,5 to 1	±5
over 1 to 2	±4
over 2 to 5	±3
over 5 to 10	±2
over 10	±1

5. Deviations permissible in the total volume of liquid medicines when manufactured by mass-volumetric method, as well as in paragraphs 7, 9, it should be borne in mind that deviations are provided for liquid medicines when manufactured using both concentrates and dry substances:

prescribed mass, ml	Deviations, %
1	2
Up to 10	±10
over 10 to 20	±8
over 20 to 50	±4
over 50 to 150	±3

over 150 to 200	±2
over 200	±1

6. Deviations permissible when packing solutions for injections made in the form of an intra-pharmaceutical preparation:

prescribed mass, ml	Deviations, %
1	2
Up to 50	±10
over 50	±5

When measuring (and filling) liquids after draining with a jet, the time is given to drain the drops: for non-viscous liquids - within one minute, for viscous liquids - within three minutes.

7. Deviations permissible when determining the content of individual medicinal substances in liquid medicines when manufactured by mass-volumetric method:

prescribed mass, gr	Deviations %
1	2
Up to 0,02	±20
over 0,02 to 0,1	±15
over 0,1 to 0,2	±10
over 0,2 to 0,5	±8
over 0,5 to 0,8	±7
over 0,8 to 1	±6
over 1 to 2	±5
over 2 to 5	±4
over 5	±3

8. Deviations permissible in the mass of liquid medicines when manufactured by the mass method:

prescribed mass, gr	Deviations %
1	2
Up to 10	±10
over 10 to 20	±8
over 20 to 50	±5
over 50 to 150	±3
over 150 to 200	±2
over 200	±1

9. Deviations permissible in the mass of incoming individual medicines in liquid medicines when manufactured by the mass method, and in ointments:

prescribed mass, gr	Deviations %
1	2
Up to 0,1	±20
over 0,1 to 0,2	±15
over 0,2 to 0,3	±12

over 0,3 to 0,5	±10
over 0,5 to 0,8	±8
over 0,8 to 1	±7
over 1 to 2	±6
over 2 to 10	±5
over 10	±3

Deviations permissible in determining the content of incoming individual medicinal substances in liquid medicines when manufactured by the mass method or mass-volumetric method, as well as in ointments, are determined not by the concentration in percent, but by the prescribed mass of the input substance in these medicines in accordance with paragraphs 7 , 9 of this Appendix.

When making 10 ml of a 2% solution of pilocarpine hydrochloride, a sample weight of 0.2 g is taken, for which a deviation of + -10% is allowed. When analyzing, it is sufficient to establish that not less than 0.18 g and not more than 0.22 g of pilocarpine hydrochloride were taken.

10. Deviations permissible in the total mass of ointments:

prescribed mass, gr	Deviations %
1	2
Up to 5	±15
over 5 to 10	±10
over 10 to 20	±8
over 20 to 30	±7
over 30 to 50	±5
over 50 to 100	±3
over 100	±2

11. Deviations permissible in concentrates with the content of the medicinal substance:

1) up to 20% not more than ± 2% of the indicated percentage;

2) over 20%, not more than ± 1% of the indicated percentage.

This paragraph indicates deviations from concentration (in percent) that are allowed in concentrates when they are manufactured both by mass-volumetric method and by mass method.

12. Deviations permissible in homeopathic triturations, solutions and dilutions of liquid medicines:

1) with a drug substance content of 10% (first decimal dilution - D1) no more than ± 5% of the indicated percentage;

2) with a drug substance content of 1% (second decimal dilution - D2) no more than ± 5% of the indicated percentage;

3) with a drug substance content of 0.1% (third decimal dilution - D3) not more than ± 10% of the indicated percentage.

This paragraph indicates deviations from concentration (in percent) that are allowed in homeopathic triturations, solutions and dilutions of liquid medicines when they are manufactured in the form of concentrates and semi-finished products.

When determining the permissible deviations in the tested medicines manufactured in the form of batches of intra-pharmaceutical preparation, the norms of deviations given in paragraphs 1-10 of this appendix should be used.

In the manufacture of medicines in the form of batches of intra-pharmaceutical preparation, the deviations permissible in the mass of input individual substances are determined by the mass of each incoming substance taken to manufacture the required volume (or mass) of a given batch (in one container from one preparation load).

When making 2 liters of 0.9% sodium chloride solution, the mass of the input substance 18 g is taken, for which a deviation of ± 3% is allowed. With chemical control, it is enough to establish that not less than 17.46 g and not more than 18.54 g of sodium chloride were taken.

Deviations permissible in the mass of input individual substances in medicines manufactured in the form of batches of intra-pharmaceutical preparation and withdrawn from the pharmacy for verification are determined as indicated in paragraph 2 and paragraph 3 above.

When considering a medicine withdrawn for inspection according to the prescription " sodium chloride solution of 0.9% - 200 ml" under chemical control, it is sufficient to establish that the solution contains not less than 1.71 g and not more than 1.89 g of sodium chloride (deviation ± 5 % according to paragraph 7 of this appendix).

13. When checking medicines manufactured in a homeopathic pharmacy according to individual prescriptions, the deviation norms given in paragraphs 1-4, 8-10 of this appendix should be used.

Appendix 2
to the Rules for manufacture of
medicines and medical products by
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Form

Norm of permissible error when measuring the value of the acid-base balance

Method of measurement	Maximum error in units of acid-base balance when measuring (measurements of acid-base balance are carried out in comparison with purified water or water for injection)	
	With interval pH 1-2	With interval pH 0,3-0,7
1	2	3
Potentiometric	0,6	0,05
Indicator paper	1	0,3

Appendix 3

to the Rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products
Form

Conditions for sterilization, storage and shelf life of medicines manufactured in a pharmacy

1. Sterile solutions in vials and bottles, hermetically sealed with rubber stoppers for running-in

№	Name	Composition	Shelf life in days at a temperature not exceeding 25ºC	Storage conditions	Sterilization mode (temperature, time)
1	2	3	4	5	6
1. Solutions for injections and infusions					
1	Analgin solution 25 %; 50 %	Analgin 250 g; 500 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
2	Apomorphine hydrochloride solution 1 %	Apomorphine hydrochloride 10 g Analgin 0.5 g Cysteine 0.2 g Hydrochloric acid solution 0.1 M-40 ml Water for injection up to 1 l	30	in a dark place, in a locker	120ºC – 8 min.
3	Atropine sulfate solution 0,05 %; 0,1 %; 1 %; 2,5 %; 5 %	Atropine sulfate 0.5 g; 1 g; 10 g; 25 g; 50 g Water for injection up to 1 l	30	in a dark place, in a locker	120ºC – 8 min.
4	Acesol solution	Sodium acetate 2 g Sodium chloride 5 g Potassium chloride 1 g Water for injection up to 1 l	30		120ºC – 8 min.
5	Water for injections		30		120ºC – 8 min.
6	Glycerin solution 10 %	Glycerin (in terms of anhydrous) 100 g Sodium chloride 9 g Water for injection up to 1 l	30		120ºC – 8 min.

7	Glucose solution 5 %; 10 %; 20 %; 25 %	Glycerin (in terms of anhydrous) 50 g; 100 g; 200 g; 250 g Hydrochloric acid solution 0.1 M to pH 3.0-4.1 Sodium chloride 0.26 g Water for injection up to 1 l	30		120ºC – 8 min.
8	Glucose solution 5% with potassium chloride 0.5% or 1%	Glucose (in terms of anhydrous) 50 g Potassium chloride 5 g or 10 g Water for injection up to 1 l	60		120ºC – 8 min.
9	Glucose solution 10% saline	Glucose (in terms of anhydrous) 10 g Potassium chloride 2 g Calcium chloride (in terms of anhydrous) 0.4 g Water for injection up to 1 l	90		120ºC – 8 min.
10	Citrate glucose solution	Glucose (in terms of anhydrous) 22.05 g Citric acid 7.3 g Sodium citrate (in terms of anhydrous) 16, 18 g (aqueous 22 g) Water for injection up to 1 l	30		120ºC – 8 min.
11	Dibazol solution 0,5 %; 1 %; 2 %	Dibazol 5 g; 10 g; 2 0 g Hydrochloric acid solution 0.1 M-10 ml Water for injection up to 1 l	60 for 0.5% and 1% 30 for 2%		120ºC – 8 min.
12	Dicain solution 0,1 %; 0,25 %; 0,3 %	Dicain 1 g; 2.5 g; 3 g Hydrochloric acid solution 0.1 M - 10 m Water for injection up to 1 l	30	in a locker	120ºC – 8 min.
13	Dicain solution 1 %; 2 %	Dicain 10 g; 20 g Sodium thiosulfate 0.5 g Water for injection up to 1 l	90	in a locker	120ºC – 8 min.

14	Diphenhydramine solution 1 %; 2 %	Diphenhydramine 10 g; 20 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
15	Disol solution	Sodium chloride 6 g Sodium acetate 2 g Water for injection up to 1 l	30		120ºC – 8 min.
16	Petrov's liquid blood substitute	Sodium chloride 15 g Potassium chloride 0.2 g Calcium chloride 1 g Water for injection up to 1 l	30		120ºC – 8 min.
17	Potassium chloride solution 0,5 %; 1 %; 3 %; 5 %; 7,5 %; 10 %	Potassium chloride 5 g; 10 g ; 30 g; 50 g; 75 g; 100 g Water for injection up to 1 l	30		120ºC – 8 min.
18	Potassium chloride solution 0.25%; 0.5%; 1% with glucose or sodium chloride	Potassium chloride 2.5 g; 5 g; 10 g Glucose (in terms of anhydrous) 50 g or sodium chloride 9 g Water for injection up to 1 l	30		120ºC – 8 min.
19	Calcium gluconate solution 10 %	Calcium gluconate 100 g Water for injection up to 1 l	7		120ºC – 8 min.
20	Calcium solution 0,25 %; 0,5 %; 1 %; 5 %; 10 %	Calcium chloride 2.5 g; 5 g; 10 g; 50 g; 100 g Water for injection up to 1 l	30		120ºC – 8 min.
21	Cardioplegic solution № 1	Sodium chloride 4.5 g Potassium chloride 2.22 g Magnesium chloride (in terms of anhydrous) 0.4 g Calcium gluconate 0.3 g Glucose (in terms of anhydrous) 1 g Mannitol 18 g Water for injection up to 1 l	6 months.		120ºC – 8 min.

22	Cardioplegic solution № 3	Sodium chloride 4.5 g Potassium chloride 1.125 g Magnesium chloride (in terms of anhydrous) 3.232 g Calcium gluconate 0.3 g Glucose (in terms of anhydrous) 1 g Mannitol 19 g Water for injection up to 1 l	12 months.		120ºC – 8 min.
23	Solution " Quartasol"	Sodium bicarbonate 1 g Sodium acetate 2.6 g Sodium chloride 4.75 g Potassium chloride 1.5 g Water for injection up to 1 l	90		120ºC – 8 min.
24	Aminocaproic acid solution 5 %	Aminocaproic acid 50 g Sodium chloride 9 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
25	Ascorbic acid solution 5 %; 10 %	Ascorbic acid 50 g; 100 g of sodium bicarbonate 23.85 g; 47.70 g Sodium sulfite anhydrous 2 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
26	Glutamic acid solution 1 %	Glutamic acid 10 g Water for injection up to 1 l	30	in a dark place	
27	Nicotinic acid solution 1 %	Nicotinic acid 10 g Sodium bicarbonate 7 g Water for injection up to 1 l	60	in a dark place	120ºC – 8 min.
28	Caffeine-benzoate solution 10 %; 20 %	Caffeine-sodium benzoate 100 g; 200 g Sodium hydroxide solution 0.1 M - 4 ml Water for injection up to 1 l	30		120ºC – 8 min.

29	Magnesium sulfate solution 10 %; 20 %; 25 %; 33 %	Magnesium sulfate 100 g; 200 g; 250 g; 330 g Water for injection up to 1 l	30		120ºC – 8 min.
30	Methylene blue solution 0,02 %; 1 %	Methylene blue 0.2 g; 10 g Water for injection up to 1 l	30		120ºC – 8 min.
31	Sodium benzoate solution 15 %	Sodium benzoate 150 g Water for injection up to 1 l	30		
32	Sodium bromide solution 5 %; 10 %; 20 %	Sodium bromide 50 g; 100 g; 200 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
33	Sodium hydrocarbonate solution 3 %;4 %; 5 %; 7 %	Sodium hydrocarbonate 30 g; 40 g; 50 g; 70 g Water for injection up to 1 l	30		120ºC – 8 min.
34	Sodium hydrocarbonate solution 3%; 4 %; 5 %; 7%; 8.4% stabilized	Sodium hydrocarbonate 30 g; 40 g; 50 g; 70 g; 84 g Trilon B 0.1 g (for 3-5% solution) 0.2 g (for 7-8.4% solution) Water for injection up to 1 l	30		120ºC – 8 min.
35	Sodium hydrocitrate solution 4 %; 5 % ; 6 %	Sodium hydrocitrite 40 g; 50 g; 60 g Water for injection up to 1 l	30		120ºC – 8 min.
36	Sodium iodide solution 5 %; 10 %; 20 %	Sodium iodide 50 g; 100 g; 200 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
37	Sodium para-aminosalicylate solution 3 %	Sodium para-aminosalicylate 30 g Sodium sulfite anhydrous 5 g Water for injection up to 1 l	7	in a dark place	120ºC – 8 min.
38	Sodium salicylate solution 3 %; 10 %	Sodium salicylate 30 g; 100 g Sodium metabisulfite 1 g	30		120ºC – 8 min.

		Water for injection up to 1 l		in a dark place	
39	Sodium chloride solution 0,45 %; 0,9 %; 5,85 %; 10 %	Sodium chloride 4.5 g; 9 g; 58.5 g; 100 g Water for injection up to 1 l	90		120ºC – 8 min.
40	Sodium citrate solution 4 %; 5 %	Sodium citrate (in terms of dry matter) 40 g; 50 g Water for injection up to 1 l	30		120ºC – 8 min.
41	Nicotinamide solution 1 %; 2 % ; 2,5 %; 5 %	Nicotinamide 10 g; 20 g; 25 g; 50 g Water for injection up to 1 l	30	in a dark place	120ºC – 8 min.
42	Novocaine solution 0,25 %; 0,5 %; 1 %; 2 %	Novocaine 2.5 g; 5 g; 10 g; 20 g Hydrochloric acid solution 0.1 M to pH 3.8-4.5 Water for injection up to 1 l	30	In a dark place	120ºC – 8 min.
43	Novocaine solution 2 %; 5 % ; 10 %	Novocaine 20 g; 50 g; 100 g Hydrochloric acid solution 0.1 M - 4 ml; 6 ml; 8 ml Sodium thiosulfate 0.5 g Water for injection up to 1 l	90	In a dark place	120ºC – 8 min.
44	Norsulfazole sodium solution 5 %; 10 %	Norsulfazole sodium (calculated on dry matter) 50 g; 100 g Water for injection up to 1 l	5 % - 30 10 % - 10	In a dark place	120ºC – 8 min.
45	Papaverine hydrochloride solution 2 %	Papaverine hydrochloride 20 g Water for injection up to 1 l	30	In a dark place	120ºC – 8 min.
46	Ringer solution	Sodium chloride 9 g Potassium chloride 0.2 g Calcium chloride 0.2 g Sodium bicarbonate 0.2 g Water for injection up to 1 l	30		120ºC – 8 min.

47	Ringer acetate solution	Sodium chloride 5.26 g Sodium acetate (in terms of anhydrous) 4.10 g Calcium chloride (in terms of anhydrous) 0.28 g Magnesium chloride (in terms of anhydrous) 0.14 g Potassium chloride 0.37 g Hydrochloric acid diluted (8%) 0.2 ml Water for injection up to 1 l	30		120ºC – 8 min.
48	Ringer-Locke solution (the drug is obtained by mixing equal volumes of two separately prepared and sterilized solutions, one of which is a solution of sodium bicarbonate, the other is glucose with salts)	Sodium chloride 9 g Potassium chloride 0.2 g Calcium chloride 0.2 g Sodium bicarbonate 0.2 g Glucose (in terms of anhydrous) 1 g Water for injection up to 1 l	The shelf life of each of the solutions is 30 days.		120ºC – 8 min.
49	Evans blue solution 0,5 %	Evans blue (anhydrous) 5 g Water for injection up to 1 l	30		120ºC – 8 min.
50	Spasmolitin solution 0,5 %; 1 %	Spasmolitin 5 g; 10 g Hydrochloric acid solution 0.1 M - 20 ml Water for injection up to 1 l	30	In a dark place	120ºC – 8 min.
51	Soluble streptocide solution 5 %; 10 %	Soluble streptocide (in terms of dry matter) 50 g; 100 g Sodium thiosulfate 1 g Water for injection up to 1 l	30	In a dark place	120ºC – 8 min.
		Trimecaine (in terms of			

52	Trimecaine solution 0,25 %; 0,5 %; 1 %; 2 %; 5 %	anhydrous) 2.5 g; 5 g; 10 g; 20 g; 50 g Sodium chloride 8.5 g; 8 g; 7 g; 5 g Water for injection up to 1 l	30+	In a dark place 5% trimecaine solution is not isotonic	120ºC – 8 min.
53	Trisol solution	Potassium chloride 1 g Sodium chloride 5 g Sodium bicarbonate 4 g Water for injection up to 1 l	30		120ºC – 8 min.
54	Furagin solution soluble 0.1% with sodium chloride 0.9%	Furagin soluble 10% with sodium chloride 90% - 10 g Water for injection up to 1 l	7	In a dark place	100ºC – 30 min.
55	Chlosal solution	Potassium chloride 1.5 g Sodium chloride 4.75 g Sodium acetate 3.6Water for injection up to 1 l	30		120ºC – 8 min.
56	Etazol sodium solution 10 %; 20 %	Etazole sodium (in terms of dry matter) 100 g; 200 g Sodium sulfite (anhydrous) 3.5 g Sodium hydrocitrate 1 g; 2 g Water for injection up to 1 l	180	In a dark place	120ºC – 8 min.
57	Ephedrine hydrochloride solution 2 %; 3 % ; 5 %	Ephedrine hydrochloride 20 g; 30 g; 50 g Water for injection up to 1 l	30	In a dark place	120ºC – 8 min.
The sterilization time is indicated for solutions with a volume of up to 100 milliliters. With an increase in the volume of the solution, the sterilization time is increased in accordance with the article "Sterilization" of the State Pharmacopoeia of the Republic of Kazakhstan.					
2. Other sterile solutions					
1	2	3	4	5	6
58	Glucose solution 50% (for intra-amneal administration)	Glucose (in terms of anhydrous) 500 g Purified water up to 1 l	90		120ºC – 8 min.

59	Boric acid solution 2 %	Boric acid 20 g Purified water up to 1 l	30		120ºC – 8 min.
60	Methyluracil solution 0,7 %	Methyluracil 7 g Purified water up to 1 l	30	In a dark place	120ºC – 8 min.
61	Sodium tetraborate solution 20% in glycerin	Sodium tetraborate 20 g Glycerin 80 g	30		120ºC – 8 min.
62	Sodium chloride solution 20% (for intra-amneal administration)	Sodium chloride 200 g Purified water up to 1 l	90		120ºC – 8 min.
63	Furacilin solution 0,01 %; 0,02 %	Furacilin 0,1 g; 0,2 g Sodium chloride 9 g Purified water up to 1 l	30	In a dark place	120ºC – 8 min.
64	Chlorhexidine bigluconate solution 0,02 %; 0,05 %	Chlorhexidine bigluconate solution 20% - 1 ml; 2.5 ml Purified water up to 1 l	90		120ºC – 8 min.
65	Ethacridine lactate solution 0,1 %	Ethacridine lactate 1 g Purified water up to 1 l	30	In a dark place	120ºC – 8 min.

2. Eye drops, ophthalmic solutions for irrigation, concentrated solutions for the manufacture of eye drops

№	Name and composition of the medicine	Shelf life in days at a temperature not higher		Storage conditions	Sterilization mode (temperature, time)	Note
		not higher than 25ºC	3-5ºC			
1	2	3	4	5	6	7
1. Eye drops						
1	Amidopyrine solution 2% Composition: Amidopyrine 0.2 g Sodium chloride 0.06 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
	Atropine sulfate solution 0.25%; 0.5%; 1 % Composition:					

2	Atropine sulfate 0.025 g ; 0.05 g; 0.1 g Sodium chloride 0.088 g; 0.085 g; 0.08 g Purified water up to 10 ml		30	In a dark place, in a locker	120ºC – 30 min.	
3	Homatropine hydrobromide solution 0.5%, 1 % Composition: Homatropine hydrobromide 0.05 g; 0.1 g Sodium chloride 0.082 g; 0.074 g Purified water 10 ml	30	30	In a dark place, in a locker	120ºC – 8 min.	
4	Dicain solution 0.25%; 0.5%; 1 % Composition: Dicain 0.025 g ; 0.05 g; 0.1 g Sodium chloride 0.085 g; 0.081 g; 0.072 g Purified water up to 10 ml		30	In a locker	100ºC – 30 min.	
5	Dicain solution 0.5%; one %; 2%; 3% Composition: Dicain 0.05% 0.1 g; 0.2 g; 0.3 g Sodium chloride 0.081 g; 0.072 g; 0.053 g; 0.035 g Sodium thiosulfate 0.005 g Purified water to 10 ml	120	0,5 % - 90 1 % - 30	In a locker	120ºC – 8 min.	A solution of dicain 0.5% is prepared without a stabilizer. A solution of dicain 2% - 3% cannot be stored in the refrigerator
6	Dicain 0.05 g Zinc sulfate	30	30		120ºC – 8 min.	

	0.05 g Boric acid solution 2% - 10 ml			In a locker		
7	Dicain 0.05 g Zinc sulfate 0.05 g Boric acid solution 2% - 10 ml Resorcinol 0.05	30	30	In a dark place, in a locker	120ºC – 8 min.	After sterilization and cooling of the solution containing dicain, boric acid, zinc sulfate, resorcinol is added under aseptic conditions
8	Diphenhydramine solution 0.25%; 0.5% Composition: Diphenhydramine 0.025 g; 0.05 g Sodium chloride 0.085 g; 0.08 g Purified water up to 10 ml	90	90	In a dark place	120ºC – 8 min.	
9	Diphenhydramine 0.02 g Boric acid solution 2% - 10 ml		30	In a dark place	120ºC – 8 min.	
10	Potassium iodide solution 3 % Composition: Potassium iodide 0.3 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
11	Potassium iodide 0.05 g Calcium chloride (in terms of anhydrous) 0.05 g Sodium chloride 0.055 g Purified water up to 10 ml	90	90	In a dark place	120ºC – 8 min.	
	Calcium chloride					

12	solution 3% Composition: Calcium chloride (in terms of anhydrous) 0.3 g Purified water up to 10 ml	30			120ºC – 8 min.	
13	Ascorbic acid solution 0.2% Composition: Ascorbic acid 0.02 g Sodium chloride 0.086 g Purified freshly boiled water to 10 ml	2	7	In a dark place	100ºC – 30 min.	
14	Clonidine solution 0.125%; 0.25%; 0.5% Composition: Clonidine 0.0125 g; 0.025 g; 0.05 g Sodium chloride 0.09 g Purified water to 10 ml	90	90	In a dark place	120ºC – 8 min.	
15	Collargol solution 2%; 3 % Composition: Collargol 0.2 g ; 0.3 g Purified water up to 10 ml	30	30	In a dark place	Prepared under aseptic conditions	The solution can be filtered through an ash-free paper filter
16	Levomycetin solution 0.2% Composition: Levomycetin 0.02 g Sodium chloride 0.09 g Purified water up to 10 ml	7	7	In a dark place	100ºC – 30 min.	
17	Levomycetin 0.01 g Boric acid solution 2% - 10 ml	7	30	In a dark place	100ºC – 30 min.	
						After sterilization

18	Levomycetin 0.02 g Zinc sulfate 0.03 g Resorcinol 0.05 g Boric acid solution 2% - 10 ml		15	In a dark place	100ºC – 30 min.	and cooling of the solution containing levomycetin, boric acid and zinc sulfate, resorcinol is added under aseptic conditions.
19	Mesatone 0.02 g Boric acid solution 2% - 10 ml	7	30	In a dark place	120ºC – 8 min.	
20	Mesatone solution 1%; 2% Ingredients : Mesatone 0.1 g; 0.2 g Sodium chloride 0.062 g; 0.034 g Purified water up to 10 ml		7	In a dark place	120ºC – 8 min.	
21	Mesatone solution 1% Composition: Mesatone 0.1 g Sodium chloride 0.056 g Sodium metabisulfite 0.01 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
22	Sodium bicarbonate 0.05 g Sodium tetraborate 0.05 g Sodium chloride 0.04 g Purified water up to 10 ml	30	30		120ºC – 8 min.	
23	Sodium iodide solution 3% Composition: Sodium iodide 0.3 g Purified water up to 10 ml	30	30	In a dark place	100ºC – 30 min.	
	Sodium iodide 0.4 g Calcium					

24	chloride (in terms of anhydrous) 0.4 g Purified water up to 10 ml	30	30	In a dark place	100ºC – 30 min.	
25	Novocaine solution 1% Composition: Novocaine 0.1 g Sodium chloride 0.072 g Purified water to 10 ml	30	30	In a dark place	100ºC – 30 min.	
26	Novocaine 0.05 g Zinc sulfate 0.02 g Resorcinol 0.1 g Boric acid solution 1% - 10 ml	10	30	In a dark place	100ºC – 30 min.	After sterilization and cooling of the solution containing novocaine, boric acid and zinc sulfate, resorcinol is added under aseptic conditions
27	Novocaine 0.05 g Zinc sulfate 0.02 g Resorcinol 0.1 g Boric acid 0.1 g Epinephrine hydrochloride solution 0.1% - 10 drops Purified water to 10 ml	10	20	In a dark place	100ºC – 30 min.	After sterilization and cooling of the solution containing novocaine, boric acid, zinc sulfate, resorcinol and adrenaline hydrochloride solution are added under aseptic conditions
28	Norsulfazole sodium solution 10% Composition: Norsulfazole sodium (in terms of dry matter) 1 g Purified water up to 10 ml	10	30	In a dark place	120ºC – 8 min.	Under the cork it is necessary to put unvarnished cellophane (GOST 7730-74), washed with purified water
	Pilocarpine hydrochloride					

29	solution 1%; 2%; four %; 6 % Composition: Pilocarpine hydrochloride 0.1 g; 0.2 g; 0.4 g; 0.6 g Sodium chloride 0.068 g; 0.046 g Purified water up to 10 ml	30	30	In a dark place, in a locker	120ºC – 8 min.	
30	Pilocarpine hydrochloride 0.1 g Boric acid solution 2% - 10 ml		30	In a dark place, in a locker	120ºC – 8 min.	
31	Riboflavin solution 0.02% Composition: Riboflavin 0.002 Sodium chloride 0.09 g Purified water to 10 ml	90	30	In a dark place	120ºC – 8 min.	
32	Riboflavin 0.001 g Ascorbic acid 0.03 g Boric acid 0.2 g Purified freshly boiled water up to 10 ml	2	7	In a dark place	100ºC – 30 min.	
33	Riboflavin 0.002 g Ascorbic acid 0.02 g Glucose (in terms of anhydrous) 0.2 g Sodium chloride 0.05 g Purified freshly boiled water up to 10 ml	2	7	In a dark place	100ºC – 30 min.	
	Riboflavin 0.002 g Potassium iodide 0.2 g Glucose (in terms of					

34	anhydrous) 0.2 g Trilon B 0.003 g Purified water up to 10 ml	30	30	In a dark place	100ºC – 30 min.	
35	Riboflavin 0.002 g Potassium iodide 0.2 g Glucose (in terms of anhydrous) 0.2 g Trilon B 0.003 g Methylcellulose solution 1% - 10 ml	30	30	In a dark place	100ºC – 30 min.	
36	Riboflavin 0.002 g Ascorbic acid 0.02 g Glucose (in terms of anhydrous) 0.2 g Sodium metabisulfite 0.01 g Trilon B 0.003 g Purified freshly boiled water up to 10 ml	7	30	In a dark place	100ºC – 30 min.	
37	Riboflavin 0.002 g Ascorbic acid 0.02 g Glucose (in terms of anhydrous) 0.2 g Sodium metabisulfite 0.01 g Trilon B 0.003 g Methylcellulose solution 1% - 10 ml	7	30	In a dark place	100ºC – 30 min.	
38	Scopolamine hydrobromide solution 0.1%; 0.25% Composition: Scopolamine Hydrobromide (in terms of anhydrous)		30	In a dark place, in a locker		

	0.01 g; 0.025 g Sodium chloride 0.09 g ; 0.087 g Purified water up to 10 ml				100ºC – 30 min.	
39	Sodium sulfapyridazine solution 10%; 20 % Composition: Sulfapyridazine sodium 1 g; 2 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
40	Sulfacyl sodium solution 20% Composition: Sulfacyl sodium 2 g Sodium metabisulfite 0.05 g Sodium hydroxide solution 1 M - 0.18 ml Purified water up to 10 ml		30	In a dark place	100ºC – 30 min.	
41	Sulfacyl sodium solution 10%; 20 %; 30% Composition: Sulfacyl sodium 1 g; 2 g; 3 g Sodium thiosulfate 0.015 g Hydrochloric acid solution 1 M - 0.035 ml Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	The solution can be used for instillation in the eyes of newborn children.
42	Fethanol solution 3%; 5 % Composition: Fetanol 0.3 g; 0.5 g Sodium chloride 0.048 g; 0.02 g	2 (3 % solution) (5 % solution)	15		120ºC – 8 min.	

	Purified water up to 10 ml			In a dark place		
43	Fethanol solution 3% Composition: Fetanol 0.3 g Sodium metabisulfite 0.01 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
44	Physostigmine salicylate solution 0.25% Composition: Physostigmine salicylate 0.025 g Nicotinic acid 0.003 g Sodium metabisulfite 0.003 g Sodium chloride 0.08 g Purified water up to 10 ml	30	30	In a dark place, in a locker	120ºC – 8 мин	
45	Solution fluorescein - sodium 0.5% Composition: Fluorescein - sodium 0.05 g Sodium chloride 0.075 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 мин	
46	Furacillin solution 0.02% Composition: Furacillin 0.002 g Sodium chloride 0.085 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
	Quinine hydrochloride solution 1% Composition: Quinine					

47	hydrochloride 0.1 g Sodium chloride 0.076 g Purified water to 10 ml	120	120	In a dark place	120ºC – 8 min.	
48	Zinc sulfate 0.03 g Novocaine 0.1 g Boric acid solution 2% - 10 ml		30	In a dark place	100ºC – 30 min.	
49	Zinc sulfate 0.025 g Diphenhydramine 0.03 g Boric acid solution 2% - 10 ml		30	In a dark place	100ºC – 30 min.	
50	Zinc sulfate 0.025 Boric acid solution 2% - 10 ml		30		120ºC – 8 min.	
51	Ethylmorphine hydrochloride solution 2% Composition: Ethylmorphine hydrochloride 0.2 g Sodium chloride 0.06 g Purified water up to 10 ml	30	30	In a dark place, in a locker	100ºC – 30 min.	
52	A solution of ephedrine hydrochloride 3 % Composition: Ephedrine hydrochloride 0.3 g Purified water up to 10 ml	30	30	In a dark place	120ºC – 8 min.	
2. Ophthalmic solutions for irrigation						
	Saline ophthalmic solution Composition: Sodium chloride 5.3 g Potassium chloride 0.75 g Calcium					

53	chloride (in terms of anhydrous) 0.48 g Sodium acetate (in terms of anhydrous) 3.9 g Glucose (in terms of anhydrous) 0, 8 g diluted hydrochloric acid (8%) 0.05 ml Purified water up to 1 l	30			120ºC – 8 min.	It is used for microsurgical operations on the eyes.
54	Saline ophthalmic solution (with magnesium chloride) Composition: Sodium chloride 5.3 g Potassium chloride 0.75 g Calcium chloride (in terms of anhydrous) 0.48 g Sodium acetate (in terms of anhydrous) 3.9 g Glucose (in terms of per anhydrous) 0.8 g Magnesium chloride (in terms of anhydrous) 0.3 g Diluted hydrochloric acid (8%) 0.05 ml Purified water up to 1 l	30			120ºC – 8 min.	It is used for microsurgical operations on the eyes.
3. Concentrated solutions for making eye drops						
55	Potassium iodide solution 20%	30		In a dark place	120ºC – 8 min.	
						The solution is made on freshly boiled purified water.

56	Ascorbic acid solution 2%; five %; ten %	5	30	In a dark place	100ºC – 30 min.	When filling the solution, the vials are filled to the top .
57	Boric acid solution 4%	30			120ºC – 8 min.	
58	Sodium thiosulfate solution 1%	30			100ºC – 30 min.	
59	Riboflavin solution 0.02%	90	30	In a dark place	120ºC – 8 min.	
60	Riboflavin 0.02 g Ascorbic acid 2 g or 10 g Purified freshly boiled water to 100 ml	5	30	In a dark place	100ºC – 30 min.	When filling the solution, the vials are filled to the top .
61	Riboflavin 0.02 g Boric acid 4 g Purified water up to 100 ml	30		In a dark place	100ºC – 30 min.	
62	Riboflavin 0.02 g Nicotinic acid 0.1 g Purified water to 100 ml	30		In a dark place	100ºC – 30 min.	
63	Zinc sulfate solution 1% or 2%	30			120ºC – 8 min.	
64	Citral solution 0.02%		2	In a dark place		Produced under aseptic conditions on sterile purified water
Opened vials with concentrates for eye drops are used within 24 hours.						

3. Medicines for newborns

№	Name and composition of the medicine	Shelf life in days at a temperature not exceeding 25 ° C	Storage conditions	Sterilization mode (temperature, time)	Note
1	2	3	4	5	6
1. Solutions for internal use					
1	Purified water	30		120ºC – 8 min.	

2	Glucose solution 5% 10% 25%	30		120ºC – 8 min.	Prepared without stabilizer
3	Glucose solution 5% - 100 ml Ascorbic acid 1 g	5	In a dark place	100ºC – 30 min.	Prepared in purified freshly boiled water. When packing, the vials are filled to the top
4	Glucose solution 10% or 20% - 100 ml Glutamic acid 1 g	30	In a dark place	120ºC – 8 min.	
5	Dibazol solution 0.01%	30		120ºC – 8 min.	
6	Diphenhydramine solution 0.02%	30	In a dark place	120ºC – 8 min.	Diphenhydramine solution should be used only in a concentration of 0.02% in a 10 ml package. In a maternity hospital, one should refrain from using diphenhydramine solutions, given its pronounced sedative effect, a depressing effect on the central nervous system and the possibility of intoxication.
7	Potassium acetate solution 0.5%	30		120ºC – 8 min.	
8	Potassium iodide solution 0.5%	30	In a dark place	120ºC – 8 min.	The packaging of the solution does not exceed 20 ml.
9	Calcium gluconate solution 1%; 3%; five %	7		120ºC – 8 min.	Dissolve in hot water.
10	Calcium lactate solution 3%; five %	30		120ºC – 8 min.	Prepared taking into account the actual moisture content of the preparation.
11		30		120ºC – 8 min.	To prepare the solution, it is

	Calcium chloride solution 3%				advisable to use a 10 - 50% concentrate.
12	Ascorbic acid solution 1%	5	In a dark place	100ºC – 30 min.	Prepared in freshly boiled purified water. When packing, the vials are filled to the top.
13	Glutamic acid solution 1%	30	In a dark place	120ºC – 8 min.	
14	Nicotinic acid solution 0.05%	30	In a dark place	120ºC – 8 min.	
15	Hydrochloric acid solution 1%	30		120ºC – 8 min.	In preparation, dilute hydrochloric acid (8.2-8.4% GF X article 18) is used, taking it as 100%
16	Caffeine-sodium benzoate solution 1%	30		120ºC – 8 min.	
17	Solution of caffeine-sodium benzoate 0.25 g or 0.5 g Sodium bromide 0.5 g or 1 g Purified water to 100 ml	30	In a dark place	120ºC – 8 min.	
18	Citric acid solution 1 g Sodium hydrocitrate 5 g Purified water to 100 ml	30		120ºC – 8 min.	
19	Magnesium sulfate solution 5%; ten %; 25%	30		120ºC – 8 min.	
20	Sodium bromide solution 1%	30	In a dark place	120ºC – 8 мин	
21	Sodium chloride solution 0.9%	30		120ºC – 8 min.	
22	Novocaine solution 0.5 g Hydrochloric acid solution 0.1 M - 0.3 ml Purified water to 100 ml	30	In a dark place	120ºC – 8 min.	

23	Pyridoxine hydrochloride solution 0.2%	30	In a dark place	120ºC – 8 min.	
24	Aminophylline solution 0.05%; 0.5%	15	In a dark place	120ºC – 8 min.	
Internal solutions for newborns are prepared on purified water.					
2. Solutions, oils for external use					
25	Brilliant green alcohol solution 1 %	2 years			
26	Potassium permanganate solution 5%	2	In a dark place	Prepared under aseptic conditions	The solution is prepared in sterile purified water, poured into sterile vials.
27	Collargol solution 2%	30	In a dark place	Prepared under aseptic conditions	The solution is prepared in sterile purified water, poured into sterile vials.
28	A solution of sodium tetraborate 10% in glycerin	30		120ºC – 8 min.	
29	Hydrogen peroxide solution 3%	15	In a dark place	Prepared under aseptic conditions	The solution is prepared in sterile purified water, poured into sterile vials, sealed with plastic stoppers and screw caps.
30	Furacilin 0.02 g Sodium chloride solution 0.9% or 10% to 100 ml	30		120ºC – 8 min.	
31	Ethacridine lactate solution 0.1%	30	In a dark place	120ºC – 8 min.	
32	Peach oil	30	In a cool, dark place	180ºC – 30 min.	The oils are sterilized in 50 ml blood bottles sealed with IR-21 rubber stoppers for running-in. The use of 25 P (red) plugs is not recommended.
33	Olive oil	30	In a cool, dark place	180ºC – 30 min.	

34	Sunflower oil	30	In a cool, dark place	180ºC – 30 min.	
35	Vaseline oil	30	In a cool, dark place	180ºC – 30 min.	
3. Eye drops					
36	Collargol solution 2%; 3%	30	In a dark place	Prepared under aseptic conditions	The solution can be filtered through an ash-free paper filter
37	Sulfacyl sodium solution 10%; 20%; 30% Composition: Sulfacyl sodium 1 g; 2 g; 3 g Sodium thiosulfate 0.015 g	30	In a dark place	120ºC – 8 min.	
	Hydrochloric acid solution 1 M 0.035 ml Purified water up to 10 ml				
4. Powders					
38	Dibazola 0.001 g Sugar (glucose) 0.2	90	In a dark place	Prepared under aseptic conditions	
39	Diphenhydramine 0.002 g Sugar (glucose) 0.2 g	90	In a dark place	Prepared under aseptic conditions	
40	Phenobarbital 0.002 g or 0.005 g Sugar (glucose) 0.2 g	90	In a dark place	Prepared under aseptic conditions	
41	Euphyllina 0.003 g Sugar 0.2 g	20	In a dark place	Prepared under aseptic conditions	It is forbidden to replace sugar in powders with euphyllin for glucose
42	Powder xeroform 10.0 g	15	In a dark place	180ºC – 30 min.	Sterilized open. The vials are sealed with treated rubber stoppers under aseptic conditions.
5. Ointments					
					Tannin is dissolved in a minimum amount

43.	Tannin ointment 1% Composition: Tannin 1 g Purified water 1 g Vaseline 98 g	20	In a cool, dark place	Prepared under aseptic conditions	of water and mixed with a sterile base. The base is sterilized at a temperature of 1800 ° C - 30 min.
44	Tannin ointment 5% Tannin composition 5 g Purified water Lanolin anhydrous 5 g each Vaseline 85 g	20	In a cool, dark place	Prepared under aseptic conditions	Tannin is dissolved in a minimum amount of water and mixed with a sterile base. The base is sterilized at a temperature of 1800 ° C - 30 min.

4. Ointments

№	Name and composition of the dosage form	Expiration date in days	Storage at a temperature of 3-5 ° C	Sterilization conditions	Note
1	2	3	4	5	6
1. Ointments					
1	Ointment containing analgin and sodium citrate Composition: Analgin 5 g Sodium citrate 10 g Emulsifier T-2 14 g Vaseline oil 12 g Vaseline 20 g Glycerin 3 g Purified water 36 g	90	In a dark place		
2	Diphenhydramine ointment 5% Composition № 1 : Diphenhydramine 5 g Vaseline 86.5 g Anhydrous lanolin 9.5 g	30	In a dark place		This composition of the base should be used if the base is not indicated when prescribing the ointment of diphenhydramine 5%. Has a superficial effect.
3	Diphenhydramine ointment 5% Composition № 2 Diphenhydramine 5 g Sunflower oil Purified water	30	In a dark place		

	Lanolin anhydrous 31.6 g each				Has a penetrating, resorptive effect.
4	Theophylline ointment 10% Composition: Theophylline 10 g Emulsifier T-2 9 g Vaseline 54 g Purified water 27 g Dimexide 10 g	1 year	In a dark place		
5	Furacillin ointment 0.2% Composition: Furacilin 0.2 g Vaseline oil 0.6 g Vaseline 99.2 g	30	In a dark place		
2. Eye ointments					
6	Base for eye ointments 100 g Composition: Anhydrous lanolin 10 g Vaseline grade for eye ointments 90 g	30	In a dark place		
7	Pilocarpine ointment 1% or 2% Composition: Pilocarpine hydrochloride 0.1 g or 0.2 g Eye ointment bases 10 g	30	In a dark place, in a locker	Prepared under aseptic conditions	
8	Thiamine ointment 0.5% or 1% Thiamine bromide composition 0.05 g or 0.1 g Eye ointment bases 10 g	30	In a dark place	Prepared under aseptic conditions	
An eye ointment base is prepared by fusing anhydrous lanolin and vaseline grade for eye ointments in a porcelain cup while heating in a water bath. The molten base is filtered through several layers of gauze, packed in dry sterilized glass jars, tied with parchment paper and sterilized in an air sterilizer at 180 ° C for 30-40 minutes or at 200 ° C for 15-25 minutes, depending on the volume of the ointment.					

5. Powders

№	Name, composition	Shelf life in days at a temperature not exceeding 25 ° C	Storage conditions	Sterilization mode	Note

1	2	3	4	5	6
1	Powders with anti-inflammatory and antacid action Aluminum hydroxide 0.35 g Magnesium oxide 0.40 g Basic bismuth nitrate 0.20 g Lactose (dextrin) 2.05 g	1 year	In a dry, dark place		
2	Dibazol 0.003 g; 0.005 g; 0.008 g Sugar (glucose) 0.2 g	90	In a dry, dark place	Prepared under aseptic conditions	For children
3	Diphenhydramine 0.005 g Sugar (glucose) 0.2 g	90	In a dry, dark place	Prepared under aseptic conditions	For children
4	Diphenhydramine 0.005 g Calcium gluconate 0.25 g Sugar (glucose) 0.1 g	1 year	In a dry, dark place	Prepared under aseptic conditions	For children
5	Calcium gluconate 0.05 g Sugar (glucose) 0.2 g	1 year	In a dry place	Prepared under aseptic conditions	For children
6	Calcium gluconate Sugar (glucose) 0.1 g each	1 year	In a dry place	Prepared under aseptic conditions	For children

6. Potions and solutions for internal use

№	Name, composition	Shelf life in days at temperature		Storage conditions	Note
		Not exceeding 25ºC	3-5ºC		
1	2	3	4	5	6
1	Quatera mixture Ingredients: Infusion of rhizomes with valerian roots from 10 g and mint leaves from 4 g - 200 ml Sodium bromide 3 g		10	In a dark place	
	Amidopyrine 0.6 g Caffeine-sodium benzoate 0.4 g				

	Magnesium sulfate 0.8 g				
2	Infusion of thermopsis herb from 0.6 g - 200 ml of Sodium bicarbonate Sodium benzoate 4 g each		10	In a dark place	
3	Hydrochloric acid solution 1% - 100 ml Pepsin 2.0		10		
4	Hydrochloric acid solution 1% or 2%	10			
5	Potassium iodide solution 0.25%	10		In orange glass vials in a dark place	
6	Novocaine solution 0.25% or 0.5%	10		In orange glass vials in a dark place	
7	Magnesium sulfate solution 10%; 25%; 33%; fifty %	15			
8	Calcium chloride solution 5% or 10%	10			
9	Ringer's solution Composition: Sodium chloride 0.9 g Sodium bicarbonate Potassium chloride Calcium chloride 0.02 g Purified water to 100 ml	5	10		
10	Mint water	30			
11	Dill water	30			

7. Concentrated solutions for the manufacture of liquid medicines

№	Name, composition	Shelf life in days at temperature		Storage conditions	Note
		Not exceeding 25ºC	3-5ºC		
1	2	3	4	5	6
1	Ammonium chloride solution 20%	15			

2	Barbital sodium solution 10%	10			
3	Hexamethylenetetramine solution 10%; 20 %; 40%	20			
4	Glucose solution 5%	2			
5	Glucose solution 10%; 20 %; 40%; fifty %	4	10		
6	Potassium bromide solution 20%	20		In a dark place	
7	Potassium iodide solution 20%	15		In a dark place	
8	Calcium chloride solution 10%; 20 %	10			
9	Calcium chloride solution 50%	30			
10	Ascorbic acid solution 5%	5			
11	Hydrochloric acid solution 10%	30			
12	Caffeine-sodium benzoate solution 5%	7	15		
13	Caffeine-sodium benzoate solution 20%	20			
14	Magnesium sulfate solution 10%; 25%; fifty %	15			
15	Sodium benzoate solution 10%	20			
16	Sodium bromide solution 20%	20		In a dark place	
17	Sodium hydrogen carbonate solution 5%	4	10		
18	Sodium salicylate solution 40%	20		In a dark place	
19	Temisala solution 10%	10		In a dark place	
20	Chloral hydrate solution 10%	5		In a dark place	

21	Chloral hydrate solution 20%	15		In a dark place	

8. Nasal drops and solutions for external use

№	Name, composition	Shelf life in days at temperature		Storage conditions	Note
		Not exceeding 25ºC	3-5ºC		
1	2	3	4	5	6
1	Diphenhydramine 0.01 g Ephedrine hydrochloride 0.1 g Menthol oil 1% 10 drops Stone seed oil 10 g	30		In a dark place	
2	Boric acid solution 2% with diphenhydramine 1% Composition: Diphenhydramine 0.1 g Boric acid 0.2 g Purified water up to 10 ml	30		In a dark place	
3	Boric acid solution 2% - 10 ml Epinephrine hydrochloride solution 0.1% - 10 drops	10	30	In a dark place	
4	Collargol solution 3%	30		In a dark place	
5	Protargol solution 2%	30		In a dark place	
6	Lugol's solution 0.25% on glycerin Composition: Iodine 0.25 g Potassium iodide 0.5 g Glycerin 98.5 g Purified water 0.75 ml	30		In orange glass vials in a dark place	
7	A solution of sodium tetraborate 20% in glycerin Composition: Sodium tetraborate 20 g Glycerin 80 g	30			
	Hydrogen peroxide solution				

8	3% Composition: Hydrogen peroxide (27.5-40%) - from 7.5 to 11 g (6.8-9.9 ml) depending on the actual content of hydrogen peroxide in the original preparation of Sodium benzoate 0.05 g Purified water up to 100 ml	2 years		In a cool, dark place	
9	Furacillin solution 0.02%	20		In a dark place	
10	A solution of soluble streptocide 0.8% with furacillin 0.01% Composition: Soluble streptocide 0.08 g Furacillin 0.001 g Sodium thiosulfate 0.01 g Purified water up to 10 ml	30		In a dark place	

9. Semi-finished products for the manufacture of external liquids, nasal drops, powders and ointments

№	Name, composition	Shelf life in days at temperature		Storage conditions	Note
		Not exceeding 25ºC	3-5ºC		
1	2	3	4	5	6
1	Diphenhydramine solution 1%	20		In a dark place	
2	Boric acid solution 2%	15	30		
3	Sodium thiosulfate solution 60%	15			
4	Sodium chloride solution 0.9%	7	15		
5	Soluble streptocide solution 0.8%	2	10	In a dark place	
	Ethacridine lactate solution				

6	0.02%; 0.05%; 0.1%; 0.2%	15			
7	Ephedrine hydrochloride solution 10%	15		In a dark place	
8	Zinc oxide Talc equally	30			
9	Zinc oxide Talc Starch equally	30			
10	Equal share of water Vaseline lanolin Ingredients: Anhydrous lanolin 168 g Vaseline 240 g Purified water 72 ml	15		In a dark place	
11	Lanolin aqueous Ingredients: Anhydrous lanolin 70 g Purified water 30 g	15		In a dark place	
12	Lanolin anhydrous Sunflower oil Purified water equally	5		In a dark place	

10. Homeopathic granules and hydroalcoholic dilutions (potencies)

№	Name, composition	Shelf life in days at temperature		Storage conditions	Note
		Not exceeding 25ºC	3-5ºC		
1	2	3	4	5	6
1	Homeopathic granules	2 years		In a dry, dark place	
2	Intermediate hydroalcoholic homeopathic dilutions (potencies)	6 months		In a dark place, in a well-sealed container	

11. Expiry dates of other medicines

№	Medicine	Shelf life no more than (days)
1	Aqueous solutions containing benzylpenicillin and glucose	1
2	Eye drops	2
3	Infusions, decoctions, mucus	2
4	Emulsions, suspensions	3

5	Injection solutions and infusions	2
6	Other medicines	10

Appendix 4
to the Rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products

Form

Register of the results of control of individual stages of manufacture of solutions for injections and infusions

Date	№ (analysis number)	№ of prescription name of the medical organization	Source drugs		Name and volume of the prepared solution	Signature of the solution maker	Filtration and packing (filling)	
			Name	Quantity				
1	2	3	4	5	6	7	8	9

Table continuation

Packer signature	Signature of the primary verifier of the mechanical additive	Sterilization				Signature of the secondary verifier of the mechanical additive	№ of analyzes before and after sterilization (indicated through slash)	Number of bottles (vials) of finished products received for release	Signature of the person who allowed the finished product to be released (the person in charge is the head of the department, pharmacist)
		Temperature	Time — from — to	Thermotest	Signature of sterilizer				
10	11	12	13	14	15	16	17	18	19

Appendix 5
to the Rules for manufacture of medicines and medical products by entities in the field of circulation of medicines and medical products licensed to manufacture medicines and medical products

Form

Register of the sterilization mode of the source medicinal substances, manufactured medicines, auxiliary materials, glassware

Date	№	Series number, prescription number, name of the medical organization with the name of the department	Name	Quantity		Sterilization conditions		Thermotest	Sterilizer's signature
				before sterilization	after sterilization	Temperature	time (indicates the start and end times of sterilization)		
1	2	3	4	5	6	7	8	9	10