

On approval of the Rules for manufacturing medicines and medical products

Invalidated Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019 № KR MHC-45. Registered in the Ministry of Justice of the Republic of Kazakhstan on April 24, 2019 № 18581.

Unofficial translation

Footnote. Expired by Order of the Minister of Health of the Republic of Kazakhstan dated 20.12.2020 No. KR MHC -286/2020 (effective after ten calendar days after the date of its first official publication).

In accordance with Article 68 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On Public Health and Health Care System", **I ORDER**:

- 1. To approve the attached Rules for manufacturing medicines and medical products.
- 2. The Committee of pharmacy of the Ministry of Healthcare of the Republic of Kazakhstan in the manner established by the legislation of the Republic of Kazakhstan shall ensure:
- 1) state registration of this order in the Ministry of Justice of the Republic of Kazakhstan;
- 2) within ten calendar days from the date of state registration of this order, sending its copy in paper and electronic form in the Kazakh and Russian languages to the Republican state enterprise on the right of economic management "Institute of legislation and legal information of the Republic of Kazakhstan" of the Ministry of Justice of the Republic of Kazakhstan for official publication and inclusion to the Standard control bank of regulatory legal acts of the Republic of Kazakhstan;
- 3) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;
- 4) within ten working days after the state registration of this order, submission of information on implementation of measures provided for in subparagraphs 1), 2) and 3) of this paragraph to the Department of legal service of the Ministry of Healthcare of the Republic of Kazakhstan.
- 3. Control over execution of this order shall be assigned to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.
- 4. This order shall be enforced upon expiry of ten calendar days after its first official publication.

Rules for manufacturing medicines and medical products Chapter 1. General provisions

- 1. These Rules for manufacturing medicines and medical products (hereinafter the Rules) shall determine the procedure for manufacturing medicines and medical products.
- 2. Manufacturing medicines and medical products shall be carried out by entities in the sphere of circulation of medicines and medical products, having the appropriate license to manufacture medicines and medical products.
 - 3. The following terms are used in these Rules:
- 1) manufacturing medicines pharmaceutical activity, related to the manufacture of medicines in pharmacies, with the acquisition of pharmaceutical substances (active pharmaceutical substances) for pharmaceutical use, storage, quality control, registration and sale of manufactured medicines;
- 2) manufacturing medical products pharmaceutical activity, related to manufacturing medical products in pharmacies, medical products stores and optics stores;
- 3) good manufacturing practice a national standard in the field of circulation of medicines and medical products, establishing requirements for organization of manufacture, manufacturing process and control in the manufacture of medicines and medical products;
- 4) sterile medical products medical products in a certain medicinal form that have passed the process of sterilization in the absence of living organisms.
- 4. Manufacturing medicines and medical products shall be carried out on the basis of medicines registered in the Republic of Kazakhstan, with the exception of medicinal substances produced in good manufacturing practice.
- 5. The technology of manufacturing medicines and medical products, produced in a pharmacy, medical products store and optics store shall be carried out in accordance with the requirements of general Articles of the State Pharmacopoeia of the Republic of Kazakhstan, individual pharmacopoeia articles, foreign pharmacopoeia recognized as valid on the territory of the Republic of Kazakhstan, regulatory documents, approved by the authorized body in the field of healthcare.
- 6. Medical organizations that do not have a pharmacy with the right to manufacture medicines shall not be allowed to manufacture and (or) package medicines, to transfer medicines from one package to another, or to replace labels.

Chapter 2. The procedure for manufacturing medicines

- 7. Medicines are manufactured taking into account the following conditions:
- 1) compliance with the rules for writing prescriptions in accordance with the Rules for writing, accounting and storage of prescriptions, approved by the order of Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 22, 2015 № 373 (registered in the Register of state registration of regulatory legal acts under № 11465), compliance with prescribed doses to a patient's age, norms of lump-sum delivery, compatibility of ingredients included in the composition of the medical product;
 - 2) compliance with manufacturing technology of medicines;
 - 3) providing the medicine with appropriate labeling and packaging;
- 4) ensuring the proper delivery of the medicine and providing the patient with objective information about the medicine with understandable terms for their use and storage.
 - 8. Manufacturing medicines shall be carried out:
 - 1) according to doctors 'prescriptions;
 - 2) according to the requirements of medical organizations;
 - 3) in the form of an intra-pharmacy preparation.
- 9. In manufacturing medicines, deviations are allowed, within the limits of the norms allowed in manufacturing medicines (including homeopathic) in the pharmacy, the permissible error in measuring the value of acid-base balance according to Appendices 1, 2 to these Rules.
- 10. The conditions for sterilization, storage and shelf life of medicines manufactured in a pharmacy are set according to Appendix 3 to these Rules.
- 11. Medicines from the pharmacy shall be delivered only to authorized medical personnel under a power of attorney issued in the manner established by the legislation of the Republic of Kazakhstan to medical organizations.
 - 12. In aseptic conditions, sterile medicines shall be manufactured, 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 of age;
- 5) medicines in the form of a liquid dosage form containing antibiotics and other antimicrobial substances, as well as 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 intra- pharmacy preparation.

- 13. It is not allowed to manufacture sterile medical products in the absence of data on chemical compatibility of medicinal substances included in them, technology and mode of sterilization.
- 14. It is not allowed to simultaneously produce several sterile solutions containing medicinal substances with different names or the same name, but in different concentrations, at the same workplace.
- 15. Results of control of separate stages of production of solutions for injections and infusions shall be registered in the registration journal of control results of separate stages of production of solutions for injections and infusions in the attached form according to Appendix 4 to these Rules. The journal is numbered, laced, signed by the head of the pharmacy and sealed with the pharmacy's seal.
- 16. Control of sterile solutions for the absence of mechanical inclusions shall be carried out before and after sterilization.

Pharmacies check the volume of solutions in vials (bottles) and the quality of their capping.

It is not allowed to scroll the metal cap "under running-in" when checking manually and pouring out the solution when tipping the vial (bottle)).

- 17. Vials with solutions after capping shall be marked by writing, stamping on the lid or using metal tokens indicating the name and concentration.
- 18. Sterilization of solutions shall be conducted no later than three hours from the start of production, under the supervision of a specialist (pharmacist or pharmaceutist).

Repeated sterilization of solutions is not allowed.

Registration of sterilization parameters shall be made in the registration journal of sterilization mode of initial medicinal substances, manufactured medical products, auxiliary materials, utensils in the form according to Appendix 5 to these Rules. The journal is numbered, laced, signed by the head of the pharmacy and sealed with the pharmacy's seal.

19. The nomenclature of concentrates, semi-finished products and intra-store preparations of medicines manufactured in the pharmacy shall be approved annually by an accredited testing laboratory, with which an agreement on control and analytical services has been concluded. This list includes medicines containing compatible active and auxiliary substances, for which there are methods of analysis for complete chemical control with established expiration dates.

Chapter 3. Procedure for manufacturing medical products

20. Medical products shall be manufactured taking into account the following conditions:

- 1) when using them for their intended purpose (during operation), in accordance with the instructions and information provided by the manufacturer of the products, safety shall be ensured and the health of patients and users shall not be at risk;
 - 2) their characteristics shall be preserved during storage and transportation;
- 3) risk of infection of patients, users, and contamination of the products themselves shall be eliminated or minimized.
- 21. Technical characteristics and functional properties of medical products are not deteriorated during the service life of the medical product, specified by the manufacturer, under the influence of external factors, and do not threaten the health and safety of patients, users during normal operation of the products in conditions, complying with the manufacturer's operating instructions.
- 22. Medical products intended for administration of drugs have compatibility with these medicines, taking into account the functional properties of medical products according to the purpose, conditions of use and storage of these drugs.
- 23. Manufacturing medical optics shall be performed on machines specially designed for processing optical lenses in accordance with a prescription issued to a specific patient.
- 24. It is mandatory to check the accuracy of manufactured glasses on special equipment (diopter) in the presence of the client, for compliance with the prescription data.

Appendix 1 to the Rules for manufacturing medicines and medical products

Norms of deviations allowed in manufacturing medicines (including homeopathic) in the pharmacy

1. Deviations allowed in the mass of individual doses when packaging powders, including powder dispensers, are determined by the prescribed dose of one powder.

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

Prescribed mass, g	Deviations %
1	2
Up to 0.1	±15
More than 0.1 to 0.3	±10
More than 0,3 to 1	±5
More than 1 to 10	±3
More than 10 to 100	±3

More than 100 to 250	±2
More than 250	±0,3

2. Deviations allowed in the total mass of homeopathic granules (including packaging) for one package:

Prescribed mass, g	Deviations %
1	2
Up to 1	±5
More than 1 to 100	±3

- 3. Deviations allowed in the mass of individual doses of suppositories and pills:
- 1) determine the average mass by weighing (up to 0.01 g) at least 10 suppositories or pills. When producing 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 sample of 5 pieces;
 - 3) it is not allowed to exceed the permissible deviations from the average mass: for suppositories \pm 5 %;

for pills weighing up to 0.3 g \pm 10 %;

for pills weighing more than $0.3 \text{ g} \pm 5 \%$.

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

Prescribed mass, g	Deviations %
1	2
Up to 0,02	±20
More than 0,02 to 0,05	±15
More than 0,05 to 0,2	±10
More than 0,2 to 0,3	±8
More than 0,3 to 0,5	±6
More than 0,5 to 1	±5
More than 1 to 2	±4
More than 2 to 5	±3
More than 5 to 10	±2
More than 10	±1

5. Deviations allowed in the total volume of liquid medicines in manufacturing by mass-volume method, as well as in subparagraphs 7, 9, it should be borne in mind that deviations are provided for liquid medicines in the manufacture with the use of both concentrates and dry substances:

Prescribed volume, ml	Deviations %
1	2
Up to 10	±10
More than 10 to 20	±8

More than 20 to 50	±4
More than 50 to 150	±3
More than 150 to 200	±2
More than 200	±1

6. Deviations, allowed when packing solutions for injection, manufactured in the form of an intra-pharmacy preparation:

Prescribed volume, ml	Deviations %
1	2
Up to 50	±10
More than 50	±5

When measuring (and packing) liquids after draining with a jet, an excerpt for draining drops is given: for non-viscous liquids – for one minute, for viscous liquids - for three minutes.

7. Deviations allowed when determining the content of individual medicinal substances in liquid medicines in the manufacture by mass-volume method:

Prescribed mass, g	Deviations %
1	2
Up to 0,02	±20
More than 0,02 to 0,1	±15
More than 0,1 to 0,2	±10
More than 0,2 to 0,5	±8
More than 0,5 to 0,8	±7
More than 0,8 to 1	±6
More than 1 to 2	±5
More than 2 to 5	±4
More than 5	±3

8. Deviations allowed in the mass of liquid medicines in the manufacture by the mass method:

Prescribed mass, g	Deviations %
1	2
Up to 10	±10
More than 10 to 20	±8
More than 20 to 50	±5
More than 50 to 150	±3
More than 150 to 200	±2
More than 200	±1

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

Prescribed mass, g	Deviations %
1 2	2
Up to 0,1 ±2	±20

More than 0,1 to 0,2	±15
More than 0,2 to 0,3	±12
More than 0,3 to 0,5	±10
More than 0,5 to 0,8	±8
More than 0,8 to 1	±7
More than 1 to 2	±6
More than 2 to 10	±5
More than 10	±3

Deviations allowed in determining the content of incoming individual medicinal substances in liquid medicines when manufactured by mass or mass-volume method, as well as in ointments, are determined not by the concentration as a percentage, but by the prescribed mass of the incoming substance in these medicines according to subparagraphs 7, 9 of this Appendix.

In manufacturing 10 ml of 2% solution of pilocarpine hydrochloride, a mass of 0.2 g shall be taken, for which a deviation of +-10 % is allowed. In the analysis, it is sufficient to establish that no less than 0.18 g and no more than 0.22 g of pilocarpine hydrochloride were taken.

10. Deviations allowed in the total mass of ointments:

10.2 4 144/10110 4110 11 4114 40 40/11 114/110 01 011/114/110.	
Prescribed mass, g	Deviations %
1	2
Up to 5	±15
More than 5 to 10	±10
More than 10 to 20	±8
More than 20 to 30	±7
More than 30 to 50	±5
More than 50 to 100	±3
More than 100	±2

11. Deviations allowed in concentrates when containing the medicinal substance: up to 20 % not more than \pm 2 % of the specified percentage;

More than 20 % no more than \pm 1 % of the specified percentage.

This paragraph specifies the deviations from the concentration (in percentages), allowed in concentrates when they are manufactured both by mass-volume method and by mass method.

- 12. Deviations, allowed in homeopathic triturations, solutions and dilutions of liquid medicines:
- 1) when the content of medicinal substance is 10 % (the first decimal dilution is D1), no more than \pm 5 % of the specified percentage;
- 2) when the content of medicinal substance is 1 % (second decimal dilution-D2), no more than ± 5 % of the specified percentage;

D3) when the content of medicinal substance is 0.1 % (third decimal dilution-D3) no more than ± 10 % of the specified percentage.

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

When determining the permissible deviations in the tested medicines, manufactured in the form of a series of intra-pharmacy preparations, the norms of deviations given in subparagraphs 1-10 of this Appendix, as well as in the current regulatory documentation regulating the manufacture and quality control of various medicines in the pharmacy should be used.

In manufacturing medicines in the form of series of intra-pharmacy preparations, the deviations, allowed in the mass of incoming individual substances are determined by the mass of each incoming substance taken for the manufacture of the required volume (or mass) of this series (in one container from one load of the medicine).

In manufacturing 2 liters of 0.9 % sodium chloride solution, the mass of the incoming substance 18 g is taken, for which a deviation of \pm 3% is allowed. During chemical control, it is sufficient to establish that no less than 17.46 g and no more than 18.54 g of sodium chloride were taken.

Deviations, allowed in the mass of incoming individual substances in medicines, manufactured in the form of series of intra-pharmacy preparations and withdrawn from the pharmacy for testing are determined as indicated above in paragraph 2 and paragraph 3.

When considering a medicine withdrawn for testing according to the prescription " 0.9% - 200 ml sodium chloride solution" during chemical control, it is sufficient to establish that the solution contains at least 1.71 g and not more than 1.89 g of sodium chloride (deviation of \pm 5% according to paragraph 7 of this Appendix).

13. When checking medicines manufactured in a homeopathic pharmacy for individual prescriptions, the norms of deviations given in paragraphs 1-4, 8-10 of this Appendix should be used.

Appendix 2 to the Rules for manufacturing medicines and medical products

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

Measurement	Maximum error in units of acid-base balance are performed in comparison with purified wa	nce when measuring (acid-base balance measurement water or water for injection)		
method	with an interval pH 1-2	with an interval pH 0,3-0,7		
1	2	3		
Potentiometric	0,6	0,05		

By indicator	1	0,3	
paper			

Appendix 3 to the Rules for manufacturing medicines and medical products

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

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№ п/ п	Name	Composition	Expiration date in days at t0 not higher than 2500C	Storage conditions	Mode of sterilization (temperature , time)
1	2	3	4	5	6
1.	Solutions for injections and infusions				
1	Solution of analgin 25 %; 50 %	Analgin 250 g; 500 g Water for injections up to 1 liter	30	In a dark place	1200C-8 min.
2	Solution of apomorphine hydrochloride 1 %	Apomorphine hydrochloride 10 g Analgin 0.5 g Cysteine 0.2 g Solution of hydrochloric acid 0.1 M-40 ml Water for injections up to 1 liter	30	In a dark place, in a lockable cabinet	1200C – 8 min.
3	Solution of atropine sulfate 0,05 %; 0,1 %; 1 %; 2,5 %; 5 %	Atropine sulfate 0.5 g; 1 g; 10 g; 25 g; 50 g Water for injections up to 1 liter	30	In a dark place, in a lockable cabinet	1200C – 8 min.
4	Solution "Atsesol"	Sodium acetate 2 g Sodium chloride 5 g Potassium chloride 1 g Water for injections up to 1 liter	30		1200C – 8 min.
5	Water for injection		30		1200C - 8 min.
		Glycerol (in terms of anhydrous) 100 g			

6	Solution of glycerol 10 %	Sodium chloride 9 g Water for injections	30		1200C – 8 min.
7	Solution of glucose 5 %; 10 %; 20 %; 25 %	up to 1 l Glycerol (in terms of anhydrous) 50 g; 100 g; 200 g; 250 g Solution of hydrochloric acid 0.1 M to pH 3.0-4.1 Sodium chloride 0.26 g Water for injections up to 1 liter	30		1200C - 8 min.
8	Solution of glucose 5 % with potassium chloride 0.5 % or 1 %	Glucose (in terms of anhydrous) 50 g Potassium chloride 5 g or 10 g Water for injections up to 1 liter	60		1200C - 8 min.
9	Solution of glucose 10% saline	Glucose (in terms of anhydrous) 10 g Potassium chloride 2 g Calcium chloride (in terms of anhydrous) 0.4 g Water for injections up to 1 liter	90		1200C - 8 min.
10	Solution of glucose citrate	Glucose (in terms of anhydrous) 22.05 g Citric acid 7.3 g Sodium citrate (in terms of anhydrous) 16, 18 g (water 22 g) Water for injections up to 1 liter	30		1200C – 8 min.
11	Solution of dibazol 0,5 %; 1 %; 2 %	Dibazole 5 g; 10 g; 20 g Acid solution hydrogen chloride 0.1 M-10 ml Water for injections up to 1 liter	60-for 0,5 % and 1 % 30-for 2 %		1200C – 8 min.
12	Solution of dikain 0.1 %; 0.25 %; 0.3 %	Dikain 1 g; 2.5 g; 3 g Solution of hydrochloric acid 0.1 M-10 m	30	In a lockable cabinet	

		Water for injections up to 1 liter			1200C - 8 min.
13	Solution of dikain 1 %; 2 %	Dikain 10 g; 20 g Sodium thiosulfate 0.5 g Water for injections up to 1 liter	90	In a lockable cabinet	1200C – 8 min.
14	Solution of diphenhydramine 1 %; 2 %	Diphenhydramine 10 g; 20 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.
15	Solution "Disol"	Sodium chloride 6 g Sodium acetate 2 g Water for injections up to 1 liter	30		1200C - 8 min.
16	Petrov's blood-replacing liquid	Sodium chloride 15 g Potassium chloride 0.2 g Calcium chloride 1 g Water for injections up to 1 liter	30		1200C – 8 min.
17	Solution of potassium chloride 0,5 %; 1 %; 3 %; 5 %; 7,5 %; 10 %	Potassium chloride 5 g; 10 g; 30 g; 50 g; 75 g; 100 g Water for injections up to 1 liter	30		1200C - 8 min.
18	Solution of potassium chloride 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 injections up to 1 liter	30		1200C - 8 min.
19	Solution of calcium gluconate 10 %	Calcium gluconate 100 g Water for injections up to 1 liter	7		1200C - 8 min.
20	Solution of calcium 0,25 %; 0,5 %; 1 %; 5 %; 10 %	Calcium chloride 2.5 g; 5 g; 10 g; 50 g; 100 g Water for injections up to 1 liter	30		1200C – 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 Mannita 18 g Water for injections up to 1 liter	6 months		1200C - 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 Mannita 19 g Water for injections up to 1 liter	12 months		1200C - 8 min.
23	Solution "Kvartasol"	S o d i u m bicarbonate 1 g Sodium acetate 2.6 g Sodium chloride 4.75 g Potassium chloride 1.5 g Water for injections up to 1 liter	90		1200C - 8 min.
24	Solution of aminocaproic acid 5 %	Aminocaproic acid 50 g Sodium chloride 9 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.
25	Solution of ascorbic acid 5 %; 10 %	Ascorbic acid 50 g; 100 g S o d i u m bicarbonate 23.85 g ; 47.70 g	30	In a dark place	1200C - 8 min.

		Sodium sulphite anhydrous 2 g Water for injections up to 1 liter			
26	Solution of glutamic acid 1 %	Glutamic acid 10 g Water for injections up to 1 liter	30	In a dark place	
27	кислоты никотиновой 1 % Solution of nicotinic acid 1 %	Nicotinic acid 10 g S o d i u m bicarbonate 7 g Water for injections up to 1 liter	60	In a dark place	1200C – 8 min.
28	Solution of caffeine-benzoate 10 %; 20 %	Caffeine-sodium benzoate 100 g; 200 g Sodium hydroxide solution 0.1 M-4 ml Water for injections up to 1 liter	30		1200C - 8 min.
29	Solution of magnesium sulfate 10 %; 20 %; 25 %; 33 %	Magnesium sulfate 100 g; 200 g; 250 g ; 330 g Water for injections up to 1 liter	30		1200C – 8 min.
30	Methylene blue solution 0.02 %; 1 %	Methylene blue 0.2 g; 10 g Water for injections up to 1 liter	30		1200C - 8 min.
31	Solution of sodium benzoate 15 %	Sodium benzoate 150 g Water for injections up to 1 liter	30		
32	Solution of sodium bromide 5 %; 10 %; 20 %	Sodium bromide 50 g; 100 g; 200 g Water for injections up to 1 liter	30	In a dark place	1200C – 8 min.
33	Solution of sodium bicarbonate 3 %;4 %; 5 %; 7 %	S o d i u m bicarbonate 30 g; 40 g; 50 g; 70 g Water for injections up to 1 liter	30		1200C - 8 min.
34	Solution of sodium bicarbonate 3 %; 4 %; 5 %; 7 %; 8,4 % stabilized	S o d i u m bicarbonate 30 g; 40 g; 50 g; 70 g; 84 g Trilona B 0.1 g (for 3-5% solution) 0.2 g (for 7-8, 4% solution)	30		

		Water for injections up to 1 liter			1200C - 8 min.
35	Solution of sodium hydrocitrate 4 %; 5 %; 6 %	S o d i u m hydrocitrate 40 g; 50 g; 60 g Water for injections up to 1 liter	30		1200C - 8 min.
36	Solution of sodium iodide 5 %; 10 %; 20 %	Sodium iodide 50 g ; 100 g; 200 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.
37	Solution of sodium paraaminosalicylate 3 %	S o d i u m paraaminosalicylate 30 g Sodium sulphite anhydrous 5 g Water for injections up to 1 liter	7	In a dark place	1200C - 8 min.
38	Solution of sodium salicylate 3 %; 10 %	Sodium salicylate 30 g; 100 g S o d i u m metabisulfite 1 g Water for injections up to 1 liter	30	In a dark place	1200C – 8 min.
39	Solution of sodium chloride 0,45 %; 0,9 %; 5,85 %; 10 %	Sodium chloride 4.5 g; 9 g; 58.5 g; 100 g Water for injections up to 1 liter	90		1200C - 8 min.
40	Solution of sodium citrate 4 %; 5 %	Sodium citrate (in terms of dry matter) 40 g; 50 g Water for injections up to 1 liter	30		1200C - 8 min.
41	Solution of nicotinamide 1 %; 2 %; 2,5 %; 5 %	Nicotinamide 10 g; 20 g; 25 g; 50 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.
42	Solution of novocaine 0,25 %; 0,5 %; 1 %; 2 %	Novocaine 2.5 g; 5 g; 10 g; 20 g Solution of hydrochloric acid 0.1 M to pH 3.8-4.5 Water for injections up to 1 liter	30	In a dark place	1200C – 8 min.
43	Solution of novocaine 2 %; 5 %; 10 %	Novocaine 20 g; 50 g; 100 g Solution of hydrochloric acid 0.1 M-4 ml; 6 ml; 8 ml	90		

		Sodium thiosulfate 0.5 g Water for injections up to 1 liter		In a dark place	1200C – 8 min.
4 4	Solution of norsulfazol-sodium 5 %; 10 %	Norsulfazol-sodium (in terms of dry matter) 50 g; 100 g Water for injections up to 1 liter	5 % - 30 10 % - 10	In a dark place	1200C – 8 min.
45	Solution of papaverine hydrochloride 2 %	Papaverine hydrochloride 20 g Water for injections up to 1 liter	30	In a dark place	1200C – 8 min.
46	Ringer's Solution	Sodium chloride 9 g Potassium chloride 0.2 g Calcium chloride 0.2 g S o d i u m bicarbonate 0.2 g Water for injections up to 1 liter	30		1200C – 8 min.
177	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	30		1200C – 8 min.
18	Ringer-Locke solution (the medicine is prepared by mixing equal volumes of two separately prepared and sterilized solutions, one of which is a solution of sodium bicarbonate, the other-glucose with salts)	Sodium chloride 9 g Potassium chloride 0.2 g Calcium chloride 0.2 g S o d i u m bicarbonate 0.2 g	The expiration date of each solution is 30 days		1200C - 8 min.

		Sodium acetate 3.6			
55	Solution "Chlosol"	Potassium chloride 1.5 g Sodium chloride 4.75 g	30		
54	Solution of soluble furagin 0.1 % with sodium chloride 0.9 %	Furagin soluble 10 % C sodium chloride 90 % - 10 g Water for injections up to 1 liter	7	In a dark place	1000C – 30 min.
3	"Trisol" solution	Potassium chloride 1 g Sodium chloride 5 g S o d i u m bicarbonate 4 g Water for injections up to 1 liter	30		1200C – 8 min.
52	Solution of trimecaine 0,25 %; 0,5 %; 1 %; 2 %; 5 %	Trimecain (in terms of 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 injections up to 1 liter	30+	In a dark place Solution o f trimecaine 5% do not isotone	1200C – 8 min.
51	Solution of soluble streptocide 5%; 10 %	Soluble streptocide (in terms of dry matter) 50 g; 100 g Sodium thiosulfate 1 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.
50	Solution of spazmolitin of 0.5 %; 1 %	Spazmolitin 5 g; 10 g Acid solution hydrogen chloride 0.1 M-20 ml Water for injections up to 1 liter	30	In a dark place	1200C – 8 min.
19	Evans blue solution 0.5 %	Evans blue (in terms of anhydrous) 5 g Water for injections up to 1 liter	30		1200 C – 8 min.
		Glucose (in terms of anhydrous) 1 g Water for injections up to 1 liter			

		Water for injections up to 1 liter			1200C - 8 min.
56	Solution of sodium ethazol 10 %; 20 %	Ethazol-sodium (in terms of dry matter) 100 g; 200 g Sodium sulphite (anhydrous) 3.5 g Sodium hydrocitrate 1 g; 2 g Water for injections up to 1 liter	180	In a dark place	1200C – 8 min.
57	Solution of ephedrine hydrochloride 2 %; 3 %; 5 %	Ephedrine hydrochloride 20 g; 30 g; 50 g Water for injections up to 1 liter	30	In a dark place	1200C - 8 min.

The sterilization holding time is indicated for solutions up to 100 milliliters. With an increase in the volume of the solution, the sterilization time is increased in accordance with Article "Sterilization" of the State Pharmacopoeia of the Republic of Kazakhstan.

2. Other sterile solutions

1	2	3	4	5	6
58	Solution of glucose 50% (for intraamneal administration)	Glucose (in terms of anhydrous) 500 g Purified water up to 1 liter	90		1200C - 8 min.
59	Solution of boric acid 2 %	Boric acid 20 g Purified water up to 1 liter	30		1200C – 8 min.
60	Solution of methyluracil 0.7 %	Methyluracil 7 g Purified water up to 1 liter	30	In a dark place	1200C – 8 min.
61	Solution of sodium tetraborate 20% in glycerin	Sodium tetraborate 20 g Glycerol 80 g	30		1200C – 8 min.
62	Solution of sodium chloride 20 % (for intraamneal administration)	Sodium chloride 200 g Purified water up to 1 liter	90		1200C - 8 min.
63	Solution of furatsilin 0,01 %; 0,02 %	Furatsilin 0.1 g; 0.2 g Sodium chloride 9 g Purified water up to 1 liter	30	In a dark place	1200C - 8 min.
64	Solution of chlorhexidine bigluconate 0.02 %;	Solution of chlorhexidine bigluconate 20 % - 1 ml; 2.5 ml	90		

	0.05 %	Purified water up to 1 liter			1200C - 8 min.	
65	Solution of ethacridine lactate 0,1 %	Ethacridine lactate 1 g Purified water up to 1 liter	30	In a dark place	1200C - 8 min.	

2. Eye drops, ophthalmic solutions for irrigation, concentrated solutions for manufacturing eye drops

1116	nanufacturing eye drops									
	Name and composition of the medicine	Expiration date in days at t		Storage	Mode of sterilization					
п/		not higher than 250C	3 - 50C	conditions	(temperature , time)	Note				
1	2	3	4	5	6	7				
1. 1	1. Eye drops									
1	Amidopyrine solution 2 % Composition: Amidopirin 0.2 g Sodium chloride 0.06 g Purified water up to 10 ml	30	30	In a dark place	1200C - 8 min.					
2	Atropine sulfate solution 0.25 %; 0.5 %; 1 % Composition: 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 lockable cabinet	1000C – 30 min.					
3	Homatropin hydrobromide solution 0.5 %, 1 % Composition: Homatropine hydrobromide 0.05 g; 0.1 g Sodium chloride 0.082 g; 0.074 g Purified water up to 10 ml	30	30	In a dark place, in a lockable cabinet	1200C - 8 min.					
	Solution of dikain 0,25 %; 0,5 %; 1 %									

4	Composition: Dikain 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 lockable cabinet	1000C - 30 min.	
5	Solution of dikain 0,5 %; 1 %; 2 %; 3 % Composition: Dikain 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 up to 10 ml	120	90 1	In a lockable cabinet	1200C – 8 min.	A solution of 0.5% dikain is prepared without a stabilizer. Solution of dikain 2 % - 3 % cannot be stored in the refrigerator
6	Dikain 0.05 g Zinc sulfate 0.05 g Solution of boric acid 2% 10 ml	30	30	In a lockable cabinet	1200C - 8 min.	
7	Dikain 0.05 g Zinc sulfate 0.05 g Solution of boric acid 2% 10 ml Resorcinol 0.05	30	30	In a dark place, in a lockable cabinet	1200C - 8 min.	After sterilization and cooling of a solution containing dikain, boric acid, and zinc sulfate, resorcinol is added under aseptic conditions
8	Solution of diphenhydramine 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	1200C – 8 min.	
9	Diphenhydramine 0.02 g Solution of boric acid 2% 10 ml Purified water up to 10 ml		30	In a dark place	1200C - 8 min.	
10	Potassium iodide solution 3 % Composition: Potassium iodide 0.3 g	30	30	In a dark place		

	Purified water up to 10 ml				1200C – 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	1200C – 8 min.	
12	Solution of calcium chloride 3 % Composition: Calcium chloride (in terms of anhydrous) 0.3 g Purified water up to 10 ml	30			1200C – 8 min.	
13	Solution of ascorbic acid 0.2 % Composition: Ascorbic acid 0.02 g Sodium chloride 0.086 g Purified fresh boiled water up to 10 ml	2	7	In a dark place	1000C - 30 min.	
14	Solution of clonidine 0.125 %; 0.25 %; 0.5 % Composition: Clonidine 0.0125 g; 0.025 g; 0.05 g Sodium chloride 0.09 g Purified water up to 10 ml	90	90	In a dark place	1200C – 8 min.	
15	Solution of collargol 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 a paper deashed filter
16	Solution of levomycetin 0.2 % Composition: Levomycetin 0.02 g	7	7			

	Sodium chloride 0.09 g Purified water up to 10 ml			In a dark place	1000C – 30 min.	
17	Levomycetin 0.01	7	30	In a dark place	1000C - 30 min.	
18	Levomycetin 0.02 g Zinc sulfate 0.03 g Resorcinol 0.05 g Solution of boric acid 2% 10 ml		15	In a dark place	1000C – 30 min.	After sterilization and cooling of a solution containing levomycetin, boric acid, and zinc sulfate, resorcinol is added under aseptic conditions.
19	Mezaton 0.02 g Solution of boric acid 2% 10 ml	7	30	In a dark place	1200C – 8 min.	
20	Solution of mezaton 1 %; 2 % Composition: Mezaton 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	1200C – 8 min.	
21	Solution of mezaton 1 % Composition: Mezaton 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	1200C - 8 min.	
22	S o d i u m bicarbonate 0.05 g Sodium tetraborate 0.05 g Sodium chloride 0.04 g Purified water up to 10 ml	30	30		1200C – 8 min.	
23	Solution of sodium iodide 3 % Composition: Sodium iodide 0.3	30	30	In a dark place		

	Purified water up to 10 ml				1000C - 30 min.	
24	Sodium iodide 0.4 g Calcium chloride (in terms of anhydrous) 0.4 g Purified water up to 10 ml	30	30	In a dark place	1000C – 30 min.	
25	Solution of novocaine 1 % Composition: Novocaine 0.1 g Sodium chloride 0.072 g Purified water up to 10 ml	30	30	In a dark place	1000C – 30 min.	
26	Novocain 0.05 g Zinc sulfate 0.02 g Resorcinol 0.1 g Solution of boric acid 1% 10 ml	10	30	In a dark place	1000C - 30 min.	After sterilization and cooling of a 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 up to 10 ml	10	20	In a dark place	1000C – 30 min.	After sterilization and cooling of a solution containing novocaine, boric acid, and zinc sulfate, resorcinol and a solution of epinephrine hydrochloride are added under aseptic conditions
28	Solution of norsulfazol sodium 10 % Composition: sodium norsulfazole (in terms of dry matter) 1 g Purified water up to 10 ml	10	30	In a dark place	1200C – 8 min.	It is necessary to put non-varnished cellophane (GOST 7730 -74) under the cork, washed with purified water
29	Pilocarpine hydrochloride solution 1 %; 2 %; 4 %; 6 % Composition: Pilocarpine hydrochloride 0.1 g ; 0.2 g; 0.4 g; 0.6 g	30	30	In a dark place, in a lockable cabinet	1200C - 8 min.	

	Sodium chloride 0.068 g; 0.046 g Purified water up to 10 ml				
30	Pilocarpine hydrochloride 0.1 g Solution of boric acid 2% 10 ml		30	In a dark place, in a lockable cabinet	1200C – 8 min.
31	Solution of riboflavin 0,02 % Composition: Riboflavin 0.002 Sodium chloride 0.09 g Purified water up to 10 ml	90	30	In a dark place	1200C – 8 min.
32	Riboflavin 0.001 g Ascorbic acid 0.03 g Boric acid 0.2 g Purified fresh boiled water up to 10 ml	2	7	In a dark place	1000C – 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 fresh boiled water up to 10 ml	2	7	In a dark place	1000C – 30 min.
34	Riboflavin 0.002 g Potassium iodide 0.2 g Glucose (in terms of anhydrous) 0.2 g Trilon b 0.003 g Purified water up to 10 ml	30	30	In a dark place	1000C – 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 Solution of methylcellulose 1 % - 10 ml	30	30	In a dark place	1000C - 30 min.

36	metabisulfite 0.01 g Trilon B 0.003 g Purified fresh boiled water up to 10 ml	7	30	In a dark place	1000C - 30 min.	
377	Riboflavin 0.002 g ascorbic acid 0.02 g Glucose (in terms of anhydrous) 0.2 g S o d i u m metabisulfite 0.01 g Trilon B 0.003 g Methylcellulose solution 1 % - 10 ml	7	30	In a dark place	1000C - 30 min.	
38	Solution of scopolamine hydrobromide 0.1 %; 0.25 % Composition: Scopolamine Hydrobromide (in terms of anhydrous), 0.01 g; 0,025 g Sodium chloride 0.09 g; 0.087 g Purified water up to 10 ml		30	In a dark place, in a lockable cabinet	1000C - 30 min.	
39	Solution of sulfapiridazin sodium 10 %; 20 % Composition: Sulfapiridazin sodium 1 g; 2 g Purified water up to 10 ml	30	30	In a dark place	1200C - 8 min.	
	Solution of sulfacyl-sodium 20 % Composition: Sulfacyl-sodium 2 g					

40	S o d i u m 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	Solution of sulfacyl-sodium 10 %; 20 %; 30 % Composition: Sulfacyl-sodium 1 g; 2 g; 3 g Sodium thiosulfate 0.015 g Solution of hydrochloric acid 1 M-0.035 ml Purified water up to 10 ml	30	30	In a dark place	1200C – 8 min.	The solution can be used for instillation into the eyes of newborn children.
42	Solution of fetanol 3 %; 5 % Composition: Fetanol 0.3 g; 0.5 g Sodium chloride 0.048 g; 0.02 g Purified water up to 10 ml	2 (3 % solution) (5 % solution)	15	In a dark place	1200C – 8 min.	
43	Solution of fetanol 3 % Composition: Fetanol 0.3 g S o d i u m metabisulfite 0.01 g Purified water up to 10 ml	30	30	In a dark place	1200C – 8 min.	
444	Solution of physostigmine salicylate 0,25 % Composition: Physostigmine salicylate 0.025 g Nicotinic acid 0.003 g Sodium metabisulfite 0.003 g Sodium chloride 0.08 g	30	30	In a dark place, in a lockable cabinet		

	Purified water up to 10 ml				1200С – 8 мин	
45	Solution of 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	1200C – 8 мин	
46	Solution of furatsilin of 0.02 % Composition: Furatsilin 0.002 g Sodium chloride 0.085 g Purified water up to 10 ml	30	30	In a dark place	1200C – 8 min.	
47	Solution of quinine hydrochloride 1 % Composition: Quinine hydrochloride 0.1 g Sodium chloride 0.076 g Purified water up to 10 ml	120	120	In a dark place	1200C – 8 min.	
48	Zinc sulfate 0.03 g Novocaine 0.1 g Solution of boric acid 2% 10 ml		30	In a dark place	1000C - 30 min.	
49	Zinc sulfate 0.025 g Diphenhydramine 0.03 g Solution of boric acid 2% 10 ml		30	In a dark place	1000C - 30 min.	
50	Zinc sulfate 0.025 Solution of boric acid 2% 10 ml		30		1200C – 8 min.	
51	Solution of ethylmorphine hydrochloride 2 % Composition: Ethylmorphine hydrochloride 0.2 g Sodium chloride 0.06 g	30	30	In a dark place, in a lockable cabinet		

	Purified water up to 10 ml				1000C - 30 min.	
52	Solution of ephedrine hydrochloride 3 % Composition: Ephedrine hydrochloride 0.3 g Purified water up to 10 ml	30	30	In a dark place	1200C – 8 min.	
2.	Ophthalmic solutions	for irrig	ation			
53	Saline ophthalmic solution 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 anhydrous) 0.8 g Diluted hydrochloric acid (8 %) 0.05 ml Purified water up to 1 liter	30			1200C – 8 min.	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 anhydrous) 0.8 g Magnesium chloride (in terms of anhydrous) 0.3 g	30			1200C – 8 min.	Used for microsurgical operations on the eyes.

Or	ened vials with eye d	lrop conc	entrate	es are used o	during the day	y.
64	Slution of citral 0,02 %		2	In a dark place		Manufactured in aseptic conditions on sterile purified water
63	Solution of zinc sulfate, 1% or 2 %	30			1200C - 8 min.	
62	Riboflavin 0.02 g Nicotinic acid 0.1 g Purified water up to 100 ml	30		In a dark place	100C - 30 min.	
61	Riboflavin 0.02 g Boric acid 4 g Purified water up to 100 ml	30		In a dark place	1000C – 30 min.	
60	Riboflavin 0.02 g Ascorbic acid 2 g or 10 g Purified fresh boiled water up to 100 ml	5	30	In a dark place	1000C - 30 min.	When filling the solution, the vials are filled to the top.
59	Solution of riboflavin 0,02 %	90	30	In a dark place	1200C - 8 min.	
58	Solution of sodium thiosulfate 1 %	30			1000C – 30 min.	
57	Solution of boric acid 4 %	30			1200C - 8 min.	
56	Solution of ascorbic acid 2 %; 5 %; 10 %	5	30	In a dark place	1000C - 30 min.	The solution is manufactured on purified fresh boiled water. When filling the solution, the vials are filled to the top.
	Solution of potassium iodide 20 %	30		In a dark place	1200C – 8 min.	
3.	Concentrated solution	ns for ma	nufact	uring eye dı	rops	
	Diluted hydrochloric acid (8 %) 0.05 ml Purified water up to 1 liter					

3. Medicines for newborns

Π/	Name and composition of the medicine	Expiration date in days at t not higher than 250C	conditions	Mode of sterilization (temperature , time)	Note
1	2	3	4	5	6
1.5	Solutions for intern	al use			

1	Purified water	30		1200C - 8 min.	
2	Solution of glucose 5 % 10 % 25 %	30		1200C - 8 min.	Prepare without stabilizer
3	Solution of glucose 5 % - 100 ml Ascorbic acid 1 g	5	In a dark place	1000C - 30 min.	Prepared on purified freshly boiled water. When packing, the vials are filled to the top
4	Solution of glucose 10 % or 20 % - 100 ml Glutamic acid 1 g	30	In a dark place	1200C - 8 min.	
5	Solution of dibazol 0,01 %	30		1200C - 8 min.	
6	Solution of dimedrol 0.02 %	30	In a dark place	1200C – 8 min.	Dimedrol solution should be used only at a concentration of 0.02 % in a 10 ml pack. In a maternity hospital, you should refrain from using dimedrol solutions, given its pronounced sedative effect, depressing effect on the central nervous system and the possibility of intoxication
7	Solution of potassium acetate of 0.5 %	30		1200C - 8 min.	
8	Solution of potassium iodide 0.5 %	30	In a dark place	1200C - 8 min.	Packing of the solution does not exceed 20 ml.
9	Solution of calcium gluconate 1 %; 3 %; 5 %	7		1200C - 8 min.	Dissolve in hot water.
10	Solution of calcium lactate 3 %; 5 %	30		1200C - 8 min.	Prepare taking into account the actual moisture content in the medicine.
11	Solution of calcium chloride 3 %	30		1200C – 8 min.	For preparation of the solution, it is advisable to use 10-50 % concentrate.
12	Solution of ascorbic acid 1 %	5	In a dark place	1000C – 30 min.	Prepared on freshly boiled purified water. When packing, the vials are filled to the top.
13	Solution of glutamic acid 1 %	30	In a dark place	1200C - 8 min.	
14	Solution of nicotinic acid 0.05 %	30	In a dark place	1200C - 8 min.	
15	Solution of hydrochloric acid 1 %	30			

				1200C – 8 min.	When preparing, diluted hydrochloric acid is used (8.2 -8.4 % GF X Article 18), taking it as 100 %
16	Solution of caffeine-sodium benzoate 1 %	30		1200C – 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 up to 100 ml	30	In a dark place	1200C – 8 min.	
18	Citric acid solution 1 g Sodium hydrocitrate 5 g Purified water up to 100 ml	30		1200C – 8 min.	
19	Solution of magnesium sulfate 5 %; 10 %;	30		1200C – 8 min.	
20	Solution of sodium bromide 1 %	30	In a dark place	1200С — 8 мин	
21	Solution of sodium chloride 0.9 %	30		1200C - 8 min.	
22	Solution of Novocaine 0.5 g Solution of Hydrochloric acid 0.1 M-0.3 ml Purified water up to 100 ml	30	In a dark place	1200C – 8 min.	
23	Solution of pyridoxine hydrochloride 0.2 %	30	In a dark place	1200C – 8 min.	
24	Solution of aminophylline of 0.05 %; 0,5 %	15	In a dark place	1200C - 8 min.	
So	lutions for internal	use for new	oorns are pr	epared with	purified water.
2.	Solutions, oils for e	xternal use			
25	Solution of Diamond green alcohol 1 %	2 years			

26	Solution of potassium permanganate 5 %	2	In a dark place	Prepared under aseptic conditions	The solution is prepared in sterile purified water and poured into sterile vials.
27	Solution of collargol 2 %	30	In a dark place	Prepared under aseptic conditions	The solution is prepared in sterile purified water and poured into sterile vials.
28	Solution of sodium tetraborate 10% in glycerin	30		1200C - 8 min.	
29	Solution of hydrogen peroxide 3 %	15	In a dark place	Prepared under aseptic conditions	The solution is prepared on sterile purified water, poured into sterile vials, capped with polyethylene plugs and screw caps.
30	Furatsilin 0.02 g Solution of sodium chloride 0.9% or 10% up to 100 ml	30		1200C – 8 min.	
31	Solution of ethacridine lactate 0,1 %	30	In a dark place	1200C - 8 min.	
32	Peach oil	30	In a cool dark place		Oils are sterilized in bottles for blood with a capacity of 50 ml, capped with rubber plugs of the brand IR – 21 for running-in. The use of plugs of brand 25 P (red) is not recommended.
33	Olive oil	30	In a cool dark place	1800C – 30 min.	
34	Sunflower oil	30	In a cool dark place	1800C – 30 min.	
35	Vaseline oil	30	In a cool dark place	1800C – 30 min.	
3.]	Eye drops				
36	Solution of collargol 2 %; 3 %	30	In a dark place	Prepared under aseptic conditions	The solution can be filtered through a paper deashed filter
37	Solution of sulfacyl-sodium 10 %; 20 %; 30 % Composition: Sulfacyl-sodium 1 g; 2 g; 3 g Sodium thiosulfate 0.015 g	30	In a dark place	1200C - 8 min.	

	Solution of hydrochloric acid 1 M 0.035 ml Purified water up to 10 ml				
4.	Powders				
38	Dibasol 0.001 g. Sugar (glucose) 0.2	90	In a dark place	Prepared under aseptic conditions	
39	Diphenhydramine is 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	Eufillina 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 eufillin to glucose
42	Powder xeroform 10.0 g	15	In a dark place	1800C – 30 min.	Sterilized in clear form. The vials are corked with treated rubber stoppers for running-in under aseptic conditions.
5.	Ointments				
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	Tannin is dissolved in a minimum amount of water and mixed with a sterile base. The base is sterilized at a temperature of 1800C-30 min.
44	Tannin ointment 5 % Composition of Tannin 5 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 1800C-30 min.

4. Ointments

π/	Name and composition of the dosage form	Expiration date in days	Storage 30- 50C	Sterilization conditions	Note
1	2	3	4	5	6
1. (Ointments				
	Ointment containing				

1	analgin and sodium citrate Composition: Analgin 5 g Sodium citrate 10 g Emulsifier T-2 14 g Vaseline oil 12 g Vaseline 20 g Glycerol 3 g Purified water 36 g	90	In a da	ark	
2	Diphenhydramine ointment 5 % Composition № 1 : Dimedrol 5 g Vaseline 86.5 g Anhydrous lanolin 9.5 g	30	In a da	ark	This composition of base should be used if the base is not specified when prescribing ointment dimedrol 5%. It has a surface effect.
3	Diphenhydramine ointment 5 % Composition № 2 Dimedrol 5 g Sunflower oil Purified water Anhydrous lanolin by 31.6 g	30	In a da	ark	It 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 da	ark	
5	Furacillin ointment 0.2 % Composition: Furacillin 0.2 g Vaseline oil 0.6 g Vaseline 99.2 g	30	In a da	ark	
2.	Base for eye ointments 100 g Composition:				

6	Anhydrous lanolin 10 g Vaseline varieties for eye ointments 90 g		In a dark place		
7	Pilocarpine ointment 1 % or 2 % Composition: Pilocarpine hydrochloride 0.1 g or 0.2 g Bases for eye ointments 10 g	30	In a dark place, in a lockable cabinet	Prepared under aseptic conditions	
8	Thiamine ointment 0.5 % or 1% Composition: Thiamine bromide 0.05 g or 0.1 g Bases for eye ointments 10 g	30	In a dark place	Prepared under aseptic conditions	

The base for eye ointments is obtained by fusing anhydrous lanolin and vaseline varieties for eye ointments in a porcelain cup when heated 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 a temperature of $180\,^{\circ}$ C for 30-40 minutes or at a temperature of $200\,^{\circ}$ C for 15-25 minutes, depending on the volume of the ointment.

5. Powders

№ п/п	Name, composition	Expiration date in days at t not higher 250C	Storage conditions	Sterilization mode	Note
1	2	3	4	5	6
1	Anti-inflammatory and antacid powders Aluminum hydroxide 0.35 g Magnesium oxide 0.40 g Bismuth nitrate basic 0.20 g Lactose (dextrin) 2.05 g	1 year	In a dry, dark place		
2	Dibasol 0,003; 0,005 g; 0.008 g Sugar (glucose) 0.2 g	90	In a dry, dark place	Prepared under a septic conditions	For children
3	Diphenhydramine 0.005 g Sugar (glucose) 0.2 g	90	In a dry, dark place	Prepared under a septic conditions	For children
1	Diphenhydramine 0.005 g. Calcium gluconate 0.25 g Sugar (glucose) 0.1 g.	1 year	In a dry, dark place	Prepared under a septic conditions	For children
5	Calcium gluconate 0.05 g. Sugar (glucose) 0.2 g.	1 year	In a dry place	Prepared under a septic conditions	For children

6	Calcium gluconate	1 year	In a dry	Prepared under	For
	Sugar (glucose) 0.1 g.		place	aseptic	children
				conditions	

6. Mixtures and solutions for internal use

	7. Whatures and solutions for internal use				
№ п/		Expiration d days at t0	late in	Storage	3.7
п	Name, composition	Expiration date in days at t0 not higher 250C 3	Note		
1	2	3	4	5	6
1	Quater mixture Composition: rhizome infusion with valerian roots of 10 g and mint leaves of 4 g-200 ml Sodium bromide 3 g		10		
	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 Sodium bicarbonate Sodium benzoate 4 g		10		
3	Solution of hydrochloric acid 1 % - 100 ml Pepsin 2.0		10		
4	Solution of hydrochloric acid 1 % or 2 %	10			
5	Solution of potassium iodide 0.25 %	10		glass vials In a dark	
6	Solution of novocaine 0,25 % or 0,5 %	10		glass vials In a dark	
7	Solution of magnesium sulfate 10 %; 25 %; 33 %; 50 %	15			
8	Solution of calcium chloride 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 up to 100 ml	5	10		
10	Mint water	30			
11	Dill water	30			
		-	-	-	-

7. Concentrated solutions for manufacturing liquid medicines

№ п/п	Name, composition	Expiration date in t0	n days at	Storage conditions	Note
		not higher 250C	3-50C	conditions	
1	2	3	4	5	6
1	Solution of ammonium chloride 20 %	15			
2	Solution of sodium barbital 10 %	10			

3	Solution of hexamethylenetetramine 10 %; 20 %; 40 %	20		
4	Solution of glucose 5 %	2		
5	Solution of glucose 10 %; 20 %; 40 %; 50 %	4	10	
6	Solution of potassium bromide 20 %	20		In a dark place
7	Solution of potassium iodide 20 %	15		In a dark place
8	Solution of calcium chloride; 20 %	10		
9	Solution of calcium chloride 50 %	30		
10	Solution of ascorbic acid 5 %	5		
11	Solution of hydrochloric acid 10 %	30		
12	Solution of caffeine-sodium benzoate 5 %	7	15	
13	Solution of caffeine-sodium benzoate 20 %	20		
14	Solution of magnesium sulfate 10 %; 25 %; 50 %	15		
15	Solution of sodium benzoate 10 %	20		
16	Solution of sodium bromide 20 %	20		In a dark place
17	Solution of sodium bicarbonate 5 %	4	10	
18	Solution of salicylate sodium 40 %	20		In a dark place
19	Solution of temisal 10 %	10		In a dark place
20	Solution of chloral hydrate 10 %	5		In a dark place
21	Solution of chloral hydrate 20 %	15		In a dark place

8. Nose drops and solutions for external use

No	Name, composition		Expiration date in days at t0			
п/п	Name, composition	n o t higher 250C	3 - 50C	conditions	Note	
1	2	3	4	5	6	
1	Dimedrol 0.01 g Ephedrine hydrochloride 0.1 g Menthol oil 1 % 10 drops Seed oil 10 g	30		In a dark place		
2	Solution of boric acid 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	Solution of boric acid 2% 10 ml Solution of adrenaline hydrochloride 0.1 % - 10 drops	10	30	In a dark place		
4	Solution of collargol 3 %	30		In a dark place		
5	Solution of protargol 2 %	30		In a dark place		
	Lugol's solution of 0.25% on the glycerol Composition:					

6	Iodine 0.25 g Potassium iodide 0.5 g Glycerol 98.5 g Purified water 0.75 ml	30	In orange glass vials In a dark place
7	Solution of sodium tetraborate 20% in glycerin Composition: Sodium tetraborate 20 g Glycerol 80 g	30	
8	Solution of hydrogen peroxide 3 % Composition: Hydrogen peroxide (27.5-40 %) - from 7.5 to 11 g (6.8-9.9 ml) depending on actual content of hydrogen peroxide in the initial preparation Sodium benzoate 0.05 g Purified water up to 100 ml	2 years	In a cool, dark place
9	Solution furacilin of 0.02 %	20	In a dark place
10	Solution of streptotsid soluble 0.8% with furacilin 0,01 % Composition: Soluble streptocide 0.08 g Furacilin 0.001 g Sodium thiosulfate 0.01 g Purified water up to 10 ml	30	In a dark place

9. Semi-finished products for manufacturing external liquids, nose drops, powders and ointments

№ п/п	Name, composition	Expiration date is t0	Storage	Note		
	, 1	not higher 250C	3-50C	conditions		
1	2	3	4	5	6	
1	Solution of dimedrol 1 %	20		In a dark place		
2	Solution of boric acid 2 %	15	30			
3	Solution of sodium thiosulfate 60 %	15				
4	Solution of sodium chloride 0.9 %	7	15			
5	Solution of soluble streptocide 0.8 %	2	10	In a dark place		
6	Solution of ethacridine lactate 0,02 %; 0,05 %; 0,1 %; 0,2 %	15				
7	Solution of ephedrine hydrochloride 10 %	15		In a dark place		
8	Zinc oxide talc equally	30				
9	Zinc oxide talc starch equally	30				
10	Lanolin water Vaseline equally Composition: Anhydrous lanolin 168 g Vaseline, 240 g Purified water 72 ml	15		In a dark place		
	Lanolin water Composition:					

11	Anhydrous lanolin 70 g	15	In a dark place
	Purified water 30 g		
	Anhydrous lanolin		
12	Sunflower oil	5	In a dark place
	Purified water equally		

10. Homeopathic granules and water-alcohol dilutions (potencies)

№ п/	Nama agunasitisu	Expiration days at t0	ate in	Stance conditions	Nata
П	Name, composition	not higher 250C	3 - 50C	Storage conditions	Note
1	2	3	4	5	6
1	Homeopathic granules	2 years		In a dry, dark place	
2	Intermediate aqueous-alcoholic homeopathic dilutions (potencies)	6 months		In a dark place, in a well corked container	

11. Expiration dates of other medicines

№ п/п	Medicine	Expiration dated 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 manufacturing
medicines and
medical products
form

Journal of registration control results for individual stages of manufacturing solutions for injections and infusions

Date	analysis number	Prescription №, name of medical organization	Initial medicines		Name and volume of the manufactured solution	Signature of the manufacturer of the solution		
1	2	3	4	5	6	7	8	9

Continuation of the table

Sterilizati	Sterilization				

				Signature					
Signature of the packer	Signature of the primary inspector of mechanical additive	Time from to	Thermotest		Signature of the secondary inspector of mechanical additive	№ of analyses before and after sterilization (indicated by a fraction)	Number of bottles (vials) of finished products received for delivery	Signature of the person who allowed the finished product to delivery (responsible person - head of the department, pharmacist)	

					of the sterilizer				
10	11	12	13	14	15	16	17	18	19

Appendix 5 to the Rules for manufacturing medicines and medical products form

Journal of registration of sterilization mode of initial medicinal substances, manufactured medicinal products, auxiliary materials and utensils

				Number Sterilization		conditions			
Date	JN⊡	series №, prescription №, name of the medical organization with the name of the department		before sterilization	after sterilization	temperature	time (start and end time of sterilization is indicated)		Signature of the sterilizer
1	2	3	4	5	6	7	8	9	10

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