

## On approval of the Rules for storage and transportation of medicines and medical devices

### *Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan dated February 16, 2021, No. ҚР ДСМ-19. Registered with the Ministry of Justice of the Republic of Kazakhstan on February 18, 2021, No. 22230.

### Unofficial translation

In accordance with paragraph 1 of Article 250 of the Code of the Republic of Kazakhstan "On the health of the people and the health care system", **I ORDER:**

**Footnote. The preamble is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

1. To approve the attached Rules for the storage and transportation of medicines and medical devices.

2. To recognize as terminated:

1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated April 24, 2015 № 262 “On approval of the Rules for the storage and transportation of medicines and medical devices” (registered in the Register of State Registration of Regulatory Legal Acts under № 11191, published on June 5, 2015, in the legal information system Adilet);

2) paragraph 4 of the List of some orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan, which is subject to changes, approved by order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019, № ҚР ДСМ-44 "On Amendments to Some Orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan” (registered in the Register of State Registration of Regulatory Legal Acts under № 18582, published on May 2, 2019, in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan ).

3. The Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall ensure:

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

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

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

4. To impose control over the execution of this order on the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into effect ten calendar days after the day of its first official publication.

*Minister of Healthcare  
of the Republic of Kazakhstan*

*A. Tsoi*

"AGREED"

Ministry of Emergency Situations  
of the Republic of Kazakhstan

" " \_\_\_\_\_ 2021

Approved  
by order of the  
Minister of Healthcare  
of the Republic of Kazakhstan  
dated February 16, 2021  
№ ҚР ДСМ-19

## **The Rules for the storage and transportation of medicines and medical devices**

### **Chapter 1. General Provisions**

1. These rules for the storage and transportation of medicines and medical devices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 1 of Article 250 of the Code of the Republic of Kazakhstan "On the Health of the People and the Healthcare System" (hereinafter referred to as the Code) and determine the procedure for the storage and transportation of medicines and medical devices.

**Footnote. Paragraph 1 – as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

2. The following terms and definitions shall be used in these Rules:

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

2) zone - a room or part of a room specially designed to perform various functions in the process of acceptance, storage and sale of medicines and medical devices;

3) shelf life of a medicinal product - the date after which the medicinal product cannot be used;

4) packaging of a medicinal product - a means or a set of means that ensures the process of circulation of medicinal products by protecting them from damage and loss, as well as protecting the environment from pollution;

5) pharmaceutical substance (active pharmaceutical substance) - a medicinal product intended for the production and manufacture of medicinal products;

6) disinfection - a set of special measures aimed at the destruction of pathogens of infectious and parasitic diseases in the external environment;

7) deratization - a set of preventive and extermination measures aimed at the destruction or reduction of the number of rodents;

8) storage in a dark place - storage of medicines and medical devices in a place protected from light;

9) storage in a dry place - storage of medicines and medical devices in rooms with a relative humidity of no more than 65 percent;

10) medical services - actions of healthcare subjects that have a preventive, diagnostic, therapeutic, palliative or rehabilitative orientation concerning a particular person;

11) medical organization - a healthcare organization, the main activity of which is the provision of medical care;

12) storage premises - specially allocated and equipped production premises intended for storage of medicines and medical devices;

13) marking - text, trademarks, conventional designation and drawings that carry information for the consumer and are applied to products (goods), documents, memos (insert sheets), labels, counter-labels, colliettes, labels, decals (stickers), packaging (container) of medicines or directly on a medical device;

14) thermal container - a box (or bag) for the transfer of medical immunobiological preparations with heat-insulating properties and a tight-fitting lid, where the optimal temperature regime (from + 20C to + 80C) shall be provided with the help of frozen refrigeration elements placed in its cavity;

15) refrigeration room (chamber) - a special sealed chamber equipped with refrigeration equipment that ensures that the required temperature regime is not lower than 0° C;

16) refrigeration element (hereinafter referred to as the Cold element) - a plastic or metal container of a rectangular shape with a hermetically sealed stopper for filling with water, which is frozen before use and serves to maintain the temperature in the container in the range from + 2° C to + 8° C;

storage, transportation.

3. Storage of medicines and medical devices shall be carried out at a certain temperature:

deep cooling - below -15° C;

in the refrigerator from +2° C to +8° C;

in a cool place from + 8° C to + 15° C;

at room temperature from +15°C to +25°C.

3-1. Storage of medicines and medical devices should be carried out at a relative humidity of no more than 65% in the storage room, unless otherwise specified in the instructions for use by the manufacturer.

**Footnote. The rules were supplemented by paragraph 3-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

4. Storage and transportation of medicines and medical devices shall be carried out under the following conditions:

1) ensuring safety, efficacy and quality throughout their entire shelf life in accordance with the conditions established by the manufacturer in the regulatory and technical document for quality control and safety of medicines in accordance with Article 231 of the Code, in the instructions for medical use for medicines and medical devices, operational documents indicated in the labelling of their packages;

2) ensuring the safety of medicines and medical devices;

3) the operational characteristics and effectiveness of the medical device do not change to such an extent as to endanger the life and health of users and third parties during the period of operation determined by the manufacturer, provided that the medical device is exposed to effects that may occur under normal operating conditions, and maintenance shall be carried out in accordance with the instructions for use.

5. Medicines and medical devices shall not be stored separately from other products to avoid any impact on them, protected from the negative effects of light, temperature, and moisture.

6. At the facilities that store medicines and medical devices, the head of the healthcare entity shall appoint a person responsible for ensuring the safety of the quality of medicines and medical devices.

7. During the storage of medicines and medical products, the responsible person carries out quality control at least once a week by visually inspecting the condition of the packaging and external changes of medicines and medical products.

**Footnote. Paragraph 7 – as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

8. Entities storing medicines and medical devices shall keep records of expiration dates on paper or electronic media.

9. Storage of medicines and medical devices shall be carried out in the premises (zones) of storage:

pharmacies, dispensaries in healthcare organizations providing primary health care and (or ) consultative and diagnostic assistance, mobile pharmacies, optics stores, medical devices; medical organization - in departments, offices and at the posts of nurses;

pharmacy warehouse, warehouse for the temporary storage of medicines and medical devices, warehouse for medical devices, and organization for the production of medicines and medical devices.

10. All medicines and medical devices, depending on the physical and physicochemical properties of exposure to various environmental factors, shall be divided into:

- 1) requiring protection from exposure to light;
- 2) requiring protection from moisture;
- 3) requiring protection from volatilization;
- 4) requiring protection from exposure to elevated temperatures;
- 5) requiring protection from low temperatures;
- 6) requiring protection from the effects of gases contained in the environment;
- 7) odorous, colouring;
- 8) flammable and explosive.

## **Chapter 2. The order of storage of medicines and medical devices**

11. Design, arrangement, composition, size of areas, equipment of premises (zones) for storage of medicines and medical devices and their operation shall ensure the safety, storage conditions for various groups of medicines and medical devices, and handling them.

Premises (zones) of storage shall ensure the implementation of operations for the acceptance, storage, and shipment of medicines and medical devices. To ensure the accuracy and safety of all operations, the storage rooms (zones) shall be provided with lighting.

The simultaneous volume of medicines and medical devices placed in the storage rooms shall not exceed 75 percent of the area of the storage rooms.

12. Finishing and floors of premises (zones) for storage of medicines have coatings that are resistant to the effects of mechanization and wet cleaning using disinfectants.

Cleanliness of storage facilities and equipment shall be kept. Equipment, inventory and materials used for cleaning (purification), as well as detergents and disinfectants, shall be stored in a separate storage room (zone) and used in such a way that they shall not become a source of contamination.

13. In the premises (zones) of storage, medicines and medical products shall be stored in their original or transport packaging.

In case of violation of the factory or transport packaging, medicines and medical products shall be placed in material cabinets, on racks, pallets, in safes in consumer and (or) in open factory packaging with the label (marking) facing out.

14. Excipients for medicines and consumables for medical devices shall be stored in their original packaging in dry, ventilated rooms in separate cabinets. After opening the factory packaging, the packaged or remaining amount of auxiliary material shall be stored in polyethylene, paper bags or thick paper bags.

15. Premises (zones) of storage shall be designed and equipped in such a way as to protect against the entry of insects, rodents or other animals, there shall be a program for preventive pest control.

16. Restrooms, dressing rooms, showers and toilets for employees shall be separated from storage rooms (zones). Food products, drinks, tobacco products, as well as medicines for personal use shall not be stored in storage rooms (zones).

Employees working in the storage area shall wear protective or work clothing appropriate for the work performed and shall also be instructed.

Temperature and humidity shall be maintained in the storage rooms, including the refrigeration room (chamber), with preliminary testing of temperature fluctuation zones (zones near the cooling system or cold air flows), with paperwork based on its results.

17. In the premises for the storage of medicines, the following shall be provided:

- 1) racks, pallets, pedestals, and cabinets for storing medicines and medical devices;
- 2) technological equipment for creating a temperature regime;
- 3) instruments for recording temperature and humidity;
- 4) means of mechanization for loading and unloading operations;
- 5) disinfectants and cleaning equipment to ensure a sanitary regime;

6) other equipment and inventory that ensures the sanitary and hygienic regime, labour protection, safety, fire safety, environmental protection and safety of medicines.

17-1. It is not allowed to store medicines near heating devices. The distance from racks, pallets, cabinets for storing medicines and medical products from the heating element should be at least 1 meter.

**Footnote. The rules were supplemented by paragraph 17-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

18. Refrigeration rooms (chambers), refrigeration devices, and refrigerators shall be equipped with devices for controlling the temperature inside the equipment (electronic devices, thermometers).

19. The equipment used to control or monitor the storage conditions of medicinal products (measuring instruments) shall be calibrated (verified). Verification of equipment (measuring instruments) shall be carried out at least once a year in accordance with subparagraph 5) of Article 19 of the Law of the Republic of Kazakhstan dated June 7, 2000 "On ensuring the uniformity of measurements".

Verification, calibration, and repair of equipment used to control or monitor the storage conditions of medicinal products shall be carried out to maintain the quality of medicinal products and eliminate negative impacts.

20. The equipment shall be in good working order and kept properly clean. Cleaning and disinfection of equipment shall be carried out in accordance with the instructions for its operation.

21. Storage rooms shall be provided with appropriate equipment for controlling temperature, and air humidity (thermometers, hygrometers and other types of devices that control air temperature and humidity). The equipment shall be placed on the inner walls of the premises away from the heating devices according to the results of testing the zones of temperature fluctuations for the cold and warm seasons. The operation of the equipment shall be carried out in accordance with the instructions attached to it.

22. The frequency of checking the monitoring of temperature and humidity in the storage rooms shall be carried out at least once a day. In each storage room, a log of temperature and relative air humidity shall be kept in the form in accordance with the annex to these Rules.

23. Medicinal products shall be stored in storage rooms separately:

1) by pharmacological groups;

2) depending on the method of application (internal, external);

3) depending on the state of aggregation;

4) in accordance with the physical and chemical properties and the influence of various environmental factors.

Medicinal products, pharmaceutical substances, and excipients shall be stored in rooms that do not allow contamination, entanglement and cross-contamination.

24. Medicinal products and medical products recognized as unsuitable for quality and safety (defective, expired, falsified, prohibited for use, suspended for medical use, etc.) shall be isolated from the rest of the products and stored in a specially designated place, protected from unauthorized access. Such products shall be marked "Not subject to further use."

25. In the production premises of pharmacies with the right to manufacture medicinal products, medicinal substances shall be stored in enamelled or glass containers in compliance with the temperature regime.

26. Medicinal products shall be stored in appropriate and marked areas, access to which shall be allowed only to authorized personnel.

27. Medicines, the decision on the treatment of which has not yet been made, returned, withdrawn from the category of suitable for delivery, in respect of which there are suspicions of falsification, recalled and rejected, are stored in isolation physically or in another reliable equivalent way (for example, electronically) from the rest of the products in a specially designated place (zone) protected from unlawful use access.

Products and their storage locations have clear designations.

**Footnote. Paragraph 27 – as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

28. Separation of zones of acceptance, quarantine, rejection, shipment and storage shall be provided.

29. In the receiving and shipping areas, weather protection shall be provided.



Shipment and acceptance areas shall be provided with equipment (ventilation (air conditioning), hygrometer, and thermometer).

In the receiving area, there shall be a zone and equipment for cleaning containers with incoming products before placing them in storage.

The control zones used to check the received products shall be allocated and provided with the appropriate equipment.

30. The room where medicines are kept in quarantine shall be marked and access shall be limited. Any system that replaces physical isolation shall provide protection in restricting access.

31. Medicinal substances that are sensitive to light shall be stored in containers made of light-protective materials (orange glass containers, metal containers, packaging made of aluminium foil or polymeric materials painted black, brown or orange) in a dark room or in cabinets with tight-fitting doors to prevent entry.

Medicinal products that require protection from the action of light shall be stored in rooms or specially equipped places that protect from natural light, packed in primary and secondary packaging, stored in cabinets or on racks, provided that measures are taken to prevent direct sunlight from reaching these medicinal products.

32. To store medicinal substances that are especially sensitive to light (silver nitrate, silver preparations, prozerin, physostigmine salicylate and the like), glass containers shall be pasted over with black opaque paper and placed in a tightly closed cabinet, painted inside with black paint.

33. Medicinal substances that require protection from exposure to atmospheric water vapour should be stored in a dry, cool place, in a tightly closed container made of materials impervious to water vapour (glass, metal, aluminium foil, thick-walled plastic containers).

34. Medicinal substances with pronounced hygroscopic properties shall be stored in a dry room in a glass container with a sealed closure, filled with paraffin on top. When closing containers with such medicinal substances, the throat and cork shall be carefully wiped.

35. Medicinal substances containing volatile substances shall be stored in a cool place in a hermetically sealed container made of materials impervious to volatile substances (glass, metal, aluminium foil).

36. Packaging and capping of medicinal substances containing volatile substances shall be carried out in a container that meets the requirements of regulatory documents.

37. Medicines requiring protection from exposure to elevated temperatures are stored at room temperature (from +15 oC to +25 oC), in a cool place (from +8 oC to +15 oC). In some cases, a lower storage temperature is required (from +2 oC to +8 oC), which is indicated on the label, in the instructions for medical use, in the regulatory document.

**Footnote. Paragraph 37 – as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**



38. Among the medicinal products that require protection from exposure to low temperatures are those whose physicochemical state changes after freezing and shall not be restored upon subsequent warming to room temperature.

Storage of medicinal products requiring protection from exposure to low temperatures shall be carried out in accordance with the temperature regime indicated on the primary and secondary packaging of the medicinal product.

39. A 40% solution of formaldehyde (formalin) shall be stored at a temperature not lower than + 9° C. When a precipitate appears, the solution shall be kept at room temperature, then the solution shall be carefully drained and used in accordance with the actual formaldehyde content.

40. Glacial acetic acid shall be stored at a temperature not lower than + 9° C. When a precipitate appears, the acid shall be kept at room temperature until the precipitate dissolves. In case the precipitate does not dissolve, the liquid part of the acid shall be drained off and used according to the actual content of acetic acid.

41. Medical fatty oils shall be stored at a temperature not lower than +10° C. When a precipitate appears, it shall be kept at room temperature, decanted and checked for compliance with all requirements of the regulatory document.

42. Medicinal substances of odorous medicinal products and dosage forms made from them in pharmacies shall be stored in isolation in a hermetically sealed container, impervious to smell, separately by name.

43. The group of colouring medicines shall include substances, their solutions, mixtures, preparations, and so on, leaving a coloured mark on containers, closures, equipment and other items, indelible by ordinary sanitary and hygienic treatment.

44. Medicinal substances of colouring substances shall be stored in a special cabinet in a tightly closed container, separately by name. To work with dyes, for each item, special weights, a mortar, and other equipment are allocated. Dosage forms made in pharmacies from medicinal substances of colouring substances should be stored on a separate shelf in a tightly closed container.

45. Medicinal plant materials containing essential oils shall be stored in isolation in a well-closed container.

46. Herbs, leaves, fruits and roots with hygroscopic properties shall be stored in glass or metal containers hermetically sealed and, if necessary, filled with paraffin (foxglove leaves, kidney tea, marshmallow root).

47. Herbal preparations shall be stored in compliance with the general rules for the storage of medicinal raw materials.

48. Medicinal plant materials are subject to periodic control in accordance with the requirements of the regulatory document. Herbs, roots, rhizomes, seeds, fruits that have lost

their normal colour, smell and the required amount of active substances, as well as those affected by mold, shall be rejected. In the presence of barn pests, depending on the degree of damage, the raw materials shall be rejected or used after processing and control.

49. Medicinal plant materials containing cardiac glycosides shall be stored in compliance with the safety of their biological activity.

50. Poisonous and potent medicinal herbal raw materials shall be stored in a separate room or a separate cabinet under lock and key.

51. Prepackaged medicinal herbal raw materials shall be stored in compliance with the storage conditions of medicinal herbal raw materials and storage conditions indicated on the packaging and instructions for use of the medicinal product for consumers (package leaflet).

Unpackaged medicinal plant raw materials shall be stored in a dry (no more than 50% humidity), well-ventilated area in a tightly closed container.

Bulk medicinal plant materials containing essential oils shall be stored in isolation in a well-closed container. Storage of medicinal plant materials containing cardiac glycosides shall be carried out in compliance with the requirement for repeated control of biological activity.

Bulk medicinal plant materials containing toxic substances shall be stored in a separate room or a separate cabinet under lock and key.

52. Storage of flammable, explosive, highly inflammable and combustible medicines and medicines that, when mixed, rubbed and exposed to elevated temperatures, can form compounds that cause ignition or explosion shall be stored, according to the principle of uniformity, in accordance with their physicochemical and flammable properties and nature packages in warehouses, divided into separate rooms (compartments), isolated from each other by blank fireproof walls (partitions).

53. In the absence of separate storage facilities for flammable substances, it is allowed to store them in common non-combustible buildings with insulation by fireproof walls from neighbouring premises that meet fire safety requirements. These rooms shall be provided with supply and exhaust ventilation.

54. Storage of flammable medicines shall be carried out separately from other medicines.

Premises for storing flammable and explosive medicines shall be provided with fireproof and stable racks and pallets. It is allowed to store flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high.

Flammable medicines shall be stored in tightly sealed strong, glass or metal containers to prevent the evaporation of liquids from the vessels.

When storing explosive medicines, measures are taken to prevent contamination with dust

55. Flammable liquids shall be stored in glass or metal containers, isolated in a separate room from other groups.

56. Flammable and combustible liquids may be stored in production storage facilities in a total amount of not more than 3 kilograms in a special metal box away from heating devices and outlets.

57. Containers intended for the storage of flammable liquids are made of glass or metal, with a tightly fitted lid to prevent evaporation of liquids. Storage of flammable and combustible substances in open containers and containers made of other materials shall not be carried out.

58. Bottles, cylinders and other large containers with flammable and combustible liquids shall be stored in containers that protect against impacts, or in cylinder tippers in one row.

It is not allowed to store them in several rows in height using different cushioning materials. It is not allowed to store these medicines near heating devices. The distance from the rack or stack to the heating element must be at least 1 m.

At workplaces, these substances shall be stored in tightly closed containers in an amount not exceeding the shift requirement.

59. Flammable and combustible liquid medicines shall not be stored:

1) in a filled container, the degree of filling is not more than 90 percent of the volume. Alcohols shall be stored in large quantities in metal containers, which fill no more than 95 percent of the volume;

2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as inorganic salts that give explosive mixtures with organic substances (potassium chlorate, potassium permanganate).

60. Flammable and explosive medicinal products shall be stored in thick-walled tightly closed containers (bottles, cans, drums), if necessary, closures are filled with paraffin.

61. Medical ether and ether for anaesthesia shall be stored in their factory packaging, in a dark, cool place, away from fire and heating devices.

**62. Excluded by Order of the Minister of Health of the Republic of Kazakhstan dated 02.06.2023 № 100 (effective ten calendar days after the date of its first official publication).**

63. When storing flammable liquids, the state of containers, their tightness and serviceability shall be constantly monitored. If violations of the primary packaging are detected, the contents shall be immediately poured into another container.

64. A container released from flammable liquids shall be left open for some time in a well-ventilated area or on the street.

65. The group of explosive medicines shall include medicines capable of generating an explosion.

Explosive medicines shall be stored in an isolated warehouse, in special rooms (compartments) separated by firewalls and ceilings, in tightly closed containers.

66. When storing explosive medicines, measures shall be taken to prevent their contamination with dust, which can cause an explosion.

67. Storage of bulk potassium permanganate shall be carried out in a special compartment in tin containers, at workplaces - in barbells with ground stoppers, separately from other organic substances.

Storage of potassium permanganate together with sulfur, organic oils, ethers, alcohol, glycerin, organic acids, and other organic substances, as well as with flammable and combustible substances shall not be carried out.

68. Bulk nitroglycerin solution shall be stored in small, well-closed glass or metal containers in a cool, dark place with precautions, away from fire. Working with nitroglycerin shall be carried out with extreme caution to prevent poisoning if it comes into contact with the skin and explosion if nitroglycerin is spilt. Nitroglycerin causes an explosion from concussion, impact and spilling alcohol solutions. Move dishes with nitroglycerin and weigh this drug in conditions that exclude spillage and evaporation of nitroglycerin, as well as its contact with the skin.

69. Storage of explosive and flammable medicines with acids and alkalis shall not be carried out.

70. When storing nitric and sulfuric acids, measures shall be taken to protect them from contact with wood, straw and other substances of organic origin.

71. In the premises for the storage of explosive and flammable medicines, in the absence of lighting, use electric lights in compliance with the rules of fire safety in accordance with the Decree of the Government of the Republic of Kazakhstan dated October 9, 2014 № 1077 "On approval of the Fire Safety Rules".

72. Joint storage of cylinders with oxygen and combustible gases, as well as storage of such cylinders in material rooms and pharmacy warehouses shall not be carried out.

73. Cylinders with oxygen and combustible gases shall be protected from heat sources, oil and other fatty substances on them and stored in isolated rooms or under sheds.

74. To maintain the quality of rubber products in storage rooms, the following conditions shall be observed:

1) maintaining a relative humidity of at least 65 percent to prevent drying, deformation and loss of elasticity;

2) isolation from exposure to chemicals: iodine, chloroform, ammonium chloride, lysol, formalin, acids, organic solvents, lubricating oils, alkalis, disinfectants, naphthalene;

3) protection from light, and sunlight;

4) protection against high (over +20°C) and low (below 0°C) air temperatures;

5) protect against ingress of flowing air (drafts, mechanical ventilation);

6) protect against mechanical damage (including squeezing, bending, twisting, and pulling).

75. Storage of certain types of rubber products shall be carried out taking into account the following features:

1) removable rubber parts included in the set of medical equipment, if it is possible to separate them from other parts without violating the integrity of the packaging of the medical device, shall be stored separately from parts made of other material;

2) products that are especially sensitive to atmospheric factors (elastic catheters, bougie, gloves, fingertips, rubber bandages, rubber stoppers) shall be stored in tightly closed boxes in separate rooms;

3) rubberized fabric (one-sided and two-sided) shall be stored in a horizontal position in rolls laid in no more than five rows, on racks, on racks with pallets;

4) elastic varnish products (catheters, bougie, probes) shall be stored in a dry room. A sign of ageing is the softening and stickiness of the surface, such products are subject to recognition as defective.

76. In the premises (zones) of storage of a pharmacy warehouse, it is allowed to store rubber products in their original packaging.

77. Plastic products shall be stored in a ventilated, dark, dry room, where there is no open flame, or vapours of volatile substances, at a distance of at least one meter from heating systems. Electrical appliances and switches are manufactured in anti-spark (fire-fighting) design. In the room where cellophane, celluloid, and aminoplast products shall be stored, the relative humidity of the air is not higher than 65 percent.

78. Contact lenses and lenses for vision correction shall be stored in consumer packaging under the conditions specified in the regulatory and technical document, in the instructions for medical use.

79. Bandage materials shall be stored in a dry, ventilated room in cabinets, boxes, racks, pallets, and trays in conditions that ensure cleanliness.

Sterile dressings (bandages, gauze pads, cotton wool, etc.) shall be stored in the original container or undamaged primary packaging.

Non-sterile dressings shall be stored in the original container or packed in thick paper.

80. Medical instruments, devices, tools, and equipment shall be stored in dry, heated rooms at room temperature. A sharp fluctuation in temperature and relative humidity in the storage rooms is not allowed. Relative humidity shall not exceed 65 percent. Relative air humidity is allowed in storage rooms in climatic zones with high humidity of up to 70 percent

81. Medical products, medical instruments and metal products shall be stored in separate cabinets, boxes and boxes with lids indicating the name of the instruments stored in them in compliance with the storage conditions specified in the regulatory and technical document and the instructions for use.

Cutting medical instruments (scalpels, knives and sharp, cutting parts) shall be stored in special nests of boxes or canisters to avoid the formation of nicks and blunting.

Medical instruments without primary packaging shall be stored in paper bags (to protect against mechanical damage and prevent contact with neighbouring objects);

Silver and nickel silver medical instruments shall be stored separately from sulfur and sulfur-containing compounds, as well as from rubber products to prevent blackening of the surface of the instruments;

Metal medical instruments shall be stored separately from medicines and rubber products, except when rubber products are an integral part of them.

Storage of metal products is subject to the following conditions:

- 1) when transferring from a cold place to a warm one, processing (wiping, lubricating) and storing them shall be carried out only after the “sweating” of the instruments stops;
- 2) when rust appears on painted metal products, they shall be removed, and the products shall be painted again.

### **Chapter 3. The procedure for transporting medicines and medical devices**

82. Vehicles and equipment used for the transportation of medicines and medical devices, corresponding to the purposes of their use and shall be equipped to protect products from undesirable effects, leading to loss of quality or violation of the integrity of the package, as well as:

- 1) not to lose the possibility of their identification and safety assessment;
- 2) not to be contaminated with other medicinal products (dosages), or substances and not contaminate themselves;
- 3) not to be exposed to environmental factors and be protected.

The vehicle and its equipment shall be kept clean and processed with detergents and disinfectants as needed.

83. During transportation, the storage conditions necessary to ensure the quality, safety and efficacy of medicines, as well as to prevent the risk of counterfeit medicines entering the supply chain shall be observed.

84. In the case of supplies of medicinal products requiring special transportation conditions, the vehicle shall be equipped with temperature control devices. Instrument readings shall be recorded throughout the transportation and documented.

85. Medicines and medical devices prepared for transportation shall be packed in group containers (cardboard boxes or stacks) with subsequent packaging in transport packaging (boxes, cartons, wrapping paper) that meets the requirements of a regulatory document and ensures the protection of medicines and medical devices from environmental factors (precipitation, dust, sunlight, mechanical damage).

All types of transport and consumer packaging, closures shall be selected depending on the properties, purpose and quantity of the medicinal product, as well as on the compatibility of the packaging material with the transported products.

86. Transportation of medicines and medical devices requiring protection from exposure to elevated temperatures shall be carried out in a thermal container with ice packs or a special transport equipped with a refrigerator.

When transporting medicinal products using dry ice, it shall be ensured that the products do not come into contact with dry ice, which negatively affects the quality of the products (for example, leads to freezing).

87. Volatile, odorous, poisonous medicines shall be packed no more than one name in one shipping package.

88. Aerosol packages during transportation shall be protected from shock and mechanical damage.

Annex  
to the Rules for the Storage  
and Transportation of Medicines  
and Medical Devices  
The form

**Journal accounting temperature and relative humidity air**

Date	Time	Indication of the device for measuring temperature (thermometer)	Indication of the instrument for measuring humidity (psychrometer, hygrometer)			Signature
			Dry instrument indication	Humidified instrument reading	Relative humidity	
1	2	3	4	5	6	7