On approval of the rules for intra-pharmaceutical control of manufactured medicinal products

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 20, 2020 No. ҚР ДСМ -287/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21835

Unofficial translation

In accordance with article 232 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and health care system" I HEREBY ORDER:

1. To approve the attached rules for intra-pharmaceutical control of manufactured medicinal products.

2. To declare invalid:

1) order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 28, 2015 No. 405 "On approval of the Rules for intra-pharmaceutical control of manufactured medicinal products" (registered in the Register of state registration of regulatory legal acts under No. 11480, published on July 23, 2015 in the information and legal system "Adilet");

2) order of the Minister of Health of the Republic of Kazakhstan dated February 7, 2017 No. 10 "On amendments and additions to the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 28, 2015 No. 405 "On approval of the Rules for intra-pharmaceutical control of manufactured medicinal products" (registered in the Register of state registration of regulatory legal acts under No. 14879, published on April 24, 2017 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 Health of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, to ensure:

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

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

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

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

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

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

Approved
by the order of the
Minister of health of the
Republic of Kazakhstan
dated December 20, 2020
№ ҚР ДСМ-287/2020

Rules for intra-pharmaceutical control of manufactured medicinal products

Chapter 1. General provisions

1. These rules for intra-pharmaceutical control of manufactured medicinal products (hereinafter referred to as the Rules) determine the procedure for intra-pharmaceutical control of manufactured medicinal products.

2. The head of the drug store appoints a pharmacist-analyst who is responsible for organizing and carrying out quality control of manufactured drugs in the drug store.

3. The head of the drug store provides the workplace of the pharmacist-analyst with a standard set of measuring instruments, test equipment, laboratory glassware, auxiliary materials used during analytical work in drug stores, in accordance with the list of standard sets of measuring instruments, test equipment, laboratory glassware, auxiliary materials, used in the conduct of analytical work in drug stores, in accordance with Appendix 1 to these Rules, as well as regulatory legal acts of the Republic of Kazakhstan in the field of circulation of medicines and medical devices.

4. Intra-pharmaceutical control is applied to medicinal products manufactured in a drug store, including intra-pharmaceutical stock, packaged products, concentrates and semi-finished products.

5. Intra-pharmaceutical control is carried out through:

1) preventive (precautionary) measures;

2) acceptance control of raw materials (drug substance, additive agent) used for manufacture of medicinal products;

3) written control;

4) selective survey control;

5) organoleptic control;

6) selective physical control;

7) chemical control;

8) control during release.

6. The results of organoleptic, selective physical control, chemical control of medicinal products are registered in the Log of registration of the results of organoleptic, selective

physical control, chemical control of intra-pharmaceutical preparations, drugs made according to recipes (requirements of medical organizations), concentrates, semi-finished products, triturations, ethyl alcohol and packing in the form according to Appendix 2 to these Rules. The pages of the Log are numbered, stitched and certified by the signature of the head of the drug store.

7. Quality control of the medicinal product manufactured in the drug store is carried out for compliance with indicators, methods and techniques in accordance with paragraph 1 of Article 240 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and health care system" (hereinafter - the Code).

Chapter 2. Preventive (precautionary) measures aimed at reducing the risk of errors and ensuring the quality of manufactured medicinal products

8. Preventive (precautionary) measures are:

1) in compliance with the conditions for aseptic preparation of medicinal products;

2) in ensuring the serviceability and accuracy of weighing instruments, carrying out their annual verification;

3) in compliance with the conditions for the receipt, collection, storage of purified water, water for injection, the correct labeling of the container in the form of an indication on the tag of the date of receipt, analysis number and signature of the person who performed the analysis ;

4) in compliance with the terms, storage conditions of reagents, standard and titrated solutions and their correct design (on the labels, in addition to the name, the concentration, molarity, date of receipt, expiration date, storage conditions, who manufactured it, are indicated);

5) in determining deviations in the tested medicinal products using measuring instruments of the same type (with the same metrological characteristics) as in their manufacture in drug stores;

6) in the processing, filling, design of the burette installation and pharmacy tare.

9. Pharmacy tare (pharmaceutical packing) is arranged as follows:

1) on the pharmacy tare with medicinal substances and additive agents contained in the storage rooms, the name, country and manufacturing plant, batch number of the manufacturing plant, number and validity of the product conformity certificate, shelf life of the medicinal substance, date of filling, signature of the person who filled in a pharmacy tare and authenticated a medicinal substance are indicated;

2) on the pharmacy tare with medicinal substances and additive agents, which are contained in the assistant room, the date of filling the pharmacy tare, the signature of the person who filled the pharmacy tare and authenticated the medicinal substance and additive agent are indicated;

3) on the pharmacy tare with narcotic drugs, psychotropic substances, precursors, toxic substances, the highest single and daily doses are additionally indicated;

4) on the pharmacy tare with medicinal substances containing cardiac glycosides, the number of units of action in one gram of medicinal plant material or in one milliliter of solution are indicated;

5) on the pharmacy tare with medicinal substances intended for manufacture of medicinal products requiring aseptic manufacturing conditions, the inscription “For sterile medicinal products” is indicated;

6) on the pharmacy tare with medicinal substances containing moisture, the percentage of moisture on cylinders with liquids (hydrogen peroxide solution, ammonia solution, formaldehyde), the actual content of the active substance is indicated;

7) pharmacy tare with solutions, tinctures and liquid semi-finished products are provided with droplets or pipettes, indicating the number of drops established by weighing in a certain volume.

Information on filling the pharmacy tare and carrying out control for authenticity of titrated solutions in a burette installation and pharmacy tare with pipettes is entered into the Log of registration of results of control of medicinal substances for authenticity in the form in accordance with Appendix 3 to these Rules. The pages of the Log are numbered, stitched, certified by the signature of the head of the drug store.

The filling of the pharmacy tare and burette in the burette installation is carried out only after the complete use of the substances contained in them and their processing.

Chapter 3. Conduct of acceptance control of raw materials (drug substance, additive agent) used for manufacture of medicinal products

10. Acceptance control of raw materials (medicinal substance, additive agent) used for manufacture of medicinal products consists of verification of the documentation characterizing the batch of products (consignment note, quality certificate of the manufacturing plant), compliance of the series on samples of medicinal substances and additive agents with series, specified in the accompanying documentation, compliance with storage conditions, transportation, as well as identification of medicinal substances and auxiliary materials according to the indicators "Packaging", "Marking" and "Description".

According to the indicator "Packaging", the integrity and compliance with the physical and chemical properties of medicinal substances and additive agents are checked.

According to the indicator "Marking", the presence on the label of the name of the manufacturer or of the company that produced the final packaging, the name of the drug substance, additive agent, its mass (volume), indicating their quantity, composition per unit of mass or volume, batch number, expiration date, packing dates are checked.

According to the "Description" indicator, the appearance, color, odor, homogeneity, absence of visible particulate matters in solutions are checked.

11. If a discrepancy is established during acceptance control according to the indicators " Packaging", "Marking", "Description", the raw materials are returned to the supplier.

Chapter 4. Written control

12. All medicinal products manufactured in the drug store are subject to written control.

13. Written control consists of filling out a checklist of arbitrary form immediately after manufacture of the medicinal product.

The checklist indicates:

1) date of manufacture;

2) the number of the recipe or the requirement of the medical organization indicating the name of the department;

3) the names of the medicinal substances taken, their quantity, total volume or weight, the number of doses; 4) the signatures of the manufacturer, who packaged and checked the medicinal product.

In the checklist, the names of narcotic drugs, poisonous, psychotropic substances, precursors are underlined with a red pencil, the letter "D" is put on medicines for children, in eye practice "Gl".

The checklist is filled out in Latin in accordance with the sequence of manufacturing technology. When filling out the checklist for homeopathic medicinal products, the names of the sequentially taken homeopathic ingredients are indicated.

In the case of using semi-finished products and concentrates, the checklist indicates their composition, concentration, volume or weight taken. In the manufacture of powders, suppositories and pills, the total weight, number and weight of individual doses are indicated. The total weight of pills or suppositories, the concentration and volume (or weight) of isotoning and stabilizing substances added to eye drops, solutions for injections and infusions is also indicated on the prescriptions.

All calculations are made before the manufacture of the medicinal product and are recorded on the back of the checklist.

The checklist indicates the calculation formulas and the coefficients of water absorption for medicinal plant materials used in this case, the coefficients of increasing the volume of solutions when dissolving medicinal substances, the coefficients of substitution in the manufacture of suppositories.

14. For medicinal products manufactured and released by the same person, a checklist is filled in during the manufacturing process of the medicinal product.

15. Checklists are kept in the drug store within thirty calendar days from the date of manufacture of the medicinal product.

16. Manufactured medicinal products, prescriptions and completed checklists are submitted for verification to a pharmacist-technologist who performs control functions for compliance with the manufacturing technology and release of medicinal products. The check consists of establishing the correspondence of the entries in the prescription checklist in the recipe, the correctness of the calculations.

Based on the results of checking the complete chemical quality control of the medicinal product, the analysis number and the signature of the pharmacist-analyst are put in the checklist.

Chapter 5. Selective survey control

17. Selective survey control is carried out after the manufacture of no more than five medicinal products by the pharmacist.

When conducting selective survey control, the pharmacist-technologist names the first substance included in the medicinal product, and in medicinal preparations of a complex composition also indicates its amount, after which the person who produced it, names all the medicinal substances taken and their amount. When using semi-finished products (concentrates), the pharmacist also names their composition and concentration.

18. If during the survey control it is established that a mistake was made in the manufacture of a medicinal product, then it is subject to physical and chemical control. If it is impossible to carry out physical and chemical control, the medicinal product is subject to destruction in accordance with paragraph 4 of Article 250 of the Code.

Chapter 6. Organoleptic control

19. Organoleptic control consists of checking the medicinal product, including homeopathic, according to the following indicators:

1) appearance;

2) color;

3) smell;

4) homogeneity;

5) absence of visible particulate matters in solutions. Medicines for internal use are tested for taste for adults - selectively, for children - mandatory.

20. The homogeneity of powders, homeopathic triturations, ointments, pills, suppositories is checked before dividing the homogeneous mass into doses in accordance with the requirements of the State Pharmacopoeia of the Republic of Kazakhstan (hereinafter – RK SP).

During a working day, each pharmacist selectively checks various types of drugs.

Chapter 7. Selective physical control

21. Selective physical control consists of checking the total weight or volume of the drug, the number and weight of individual doses included in this drug (but not less than three doses), and the quality of the closure.

The following is subject to selective physical control:

1) each series of packaging of industrial products and intra-pharmaceutical stock in the amount of three to five packages, including packaging of homeopathic medicinal products for compliance with the deviation rate permissible in the manufacture of medicinal products (including homeopathic ones) in the drug store and the deviation rate permissible for packaging of industrial products;

2) at least three percent of medicinal products made according to prescriptions (requirements) in one working day;

3) the number of homeopathic granules in a certain sample weight;

4) each series of medicinal products requiring sterilization, after pre-packing before sterilization, in the amount of at least five vials (bottles) for particulate matters (mobile insoluble substances, except for gas bubbles, accidentally present in solutions).

22. During the manufacturing process, solutions are subjected to primary and secondary control for particulate matters:

1) the primary control is carried out after filtration and pre-packing of the solution. At the same time, each bottle or vial of solution is viewed. If particulate matters are found, the solution is re-filtered, sealed, re-examined, labeled and sterilized. Solutions made under aseptic conditions are inspected once after filling or sterilizing filtration;

2) all bottles and vials with solutions that have passed the stage of sterilization are subject to secondary control before registration and packaging.

23. To view the bottles (vials) in the prescription-production department of the drug store, a special workplace is created, protected from direct sunlight, where the device "Device for monitoring solutions for the absence of particulate matters" is installed. A black-and-white screen is used, illuminated in such a way as to exclude light into the eyes directly from its source.

24. Control is carried out by a pharmacist-technologist by viewing solutions with the naked eye on black and white backgrounds, illuminated by an electric matt lamp of sixty watts or a fluorescent lamp of twenty watts, for colored solutions on a black background - one hundred watts, on white - thirty watts. The distance from the eye to the object being viewed is twenty-five to thirty centimeters, and the angle of the optical viewing axis to the direction of light is about ninety degrees. The line of sight goes to the bottom with the head upright.

25. Bottles and vials being viewed have a clean and dry exterior.

26. Depending on the volume of the bottle or vial, from one to five pieces are examined simultaneously. Bottles or vials are taken in one or both hands by the necks, brought into the control zone, turned upside down in a smooth motion and viewed against black and white

backgrounds. Then, with a smooth movement, without shaking, it is turned over to its original position “bottom-down” and also viewed against black and white backgrounds.

27. The control time, excluding the time for auxiliary operations, is:

1) one bottle (vial) with a capacity of one hundred to five hundred milliliters - up to twenty seconds;

2) two bottles (vials) with a capacity of fifty to one hundred milliliters - ten seconds;

3) from two to five bottles (vials) with a capacity of fifty milliliters - within eight to ten seconds.

28. Bottles or vials rejected due to the presence of particulate matters are selected and placed separately in a special container. They are opened and emptied.

Chapter 8. Chemical control

29. Chemical control consists of assessment of the quality of manufacturing of medicinal products in terms of:

1) authenticity, purity tests and impurity limits (qualitative analysis);

2) quantitative determination (quantitative analysis) of medicinal substances included in its composition.

30. The following is subject to qualitative analysis:

1) purified water, water for injection daily (from each cylinder, and when water is supplied through the pipeline at each workplace) for the absence of chlorides, sulfates and calcium salts.

Water for injection intended for medicinal products requiring aseptic manufacturing conditions, in addition to the tests indicated above, must be checked for the absence of reducing substances, ammonium salts and carbonic anhydride in accordance with the requirements of the RK SP.

The results of the qualitative analysis are recorded in the Log of registration of the results of the control of purified water and water for injection in the form in accordance with Appendix 4 to these Rules, the pages of which are numbered, stitched, certified by the signature of the head of the drug store;

2) all medicinal products, concentrates and semi-finished products (including homeopathic tinctures, triturations, solutions, dilutions) coming from the storage rooms to the assistant room, and in case of doubt - medicinal substances coming to the drug store from the supplier's warehouse;

3) concentrates, semi-finished products and liquid medicinal substances in a burette installation and in pharmacy tare with pipettes in the assistant room during filling;

4) medicinal products of industrial production, packaged in a drug store, intra-pharmaceutical stock, produced and packaged in a drug store (each batch).

31. The following is subject to qualitative analysis selectively:

1) medicinal products made according to prescriptions and requirements of medical organizations. Each pharmacist checks at least ten percent of the total number of manufactured drugs during the working day;

2) medicinal products for children, medicinal products used in ophthalmic practice, containing narcotic drugs, psychotropic substances, precursors, poisonous substances, homeopathic remedies up to the fourth decimal dilution, containing toxic, inorganic and organic.

32. The results of the qualitative analysis are registered in the Log of registration of the results of control of medicinal substances for authenticity in accordance with Appendix 3 to these Rules.

33. The following is subject to complete chemical control (qualitative and quantitative analysis):

1) solutions for injections and infusions before sterilization, including the determination of the acid-base balance (pH), isotonizing and stabilizing substances.

For control after sterilization, one bottle is selected from each batch and checked for the value of the acid-base balance, authenticity and quantitative content of active substances;

2) sterile solutions for external use (ophthalmic solutions for irrigation, solutions for treatment of burn surfaces and open wounds, for intravaginal introduction, and others);

3) eye drops and ointments, the content of isotoning and stabilizing substances in which is determined before sterilization;

4) medicinal products for newborns (in the absence of quantitative analysis methods, these medicinal products are subject to qualitative analysis).

The manufacture of drugs of complex composition for newborn children that do not have methods of qualitative and quantitative analysis is carried out under the supervision of a pharmacist-analyst;

5) solutions of atropine sulfate and hydrochloric acid (for internal use), solutions of mercury dichloride and silver nitrate;

6) concentrates, semi-finished products, triturations, including liquid homeopathic dilutions of inorganic and organic medicinal substances and their trituration up to the third decimal dilution. The manufacture of homeopathic medicines that do not have methods of qualitative and quantitative analysis is carried out under the supervision of a pharmacist-analyst;

7) intra-pharmaceutical stock of medicinal products (each batch);

8) stabilizers used in the manufacture of solutions for injections and buffer solutions used in the manufacture of eye drops;

9) concentration of ethyl alcohol by determining the density (with an alcohol meter) when diluted in a drug store, and, if necessary, when taken from the supplier's warehouse;

10) concentration of ethyl alcohol in aqueous-alcoholic homeopathic solutions, dilutions and drops (each batch);

11) homeopathic granules for disintegration (each batch).

34. Medicinal products manufactured in a drug store according to prescriptions or requirements of medical organizations, in the amount of at least three medicinal products per shift, are selectively subjected to complete chemical control (qualitative and quantitative analysis).

Medicinal products for children used in eye practice, containing narcotic drugs, psychotropic substances, precursors and toxic substances, as well as solutions for medicinal enemas, require special attention.

35. A complete chemical analysis of treated water is carried out on a quarterly basis.

36. Manufacturing of aromatic waters, pharmaceutical stock for external use, pharmaceuticals containing tar, ichthyol, sulfur, Naftalan oil, collodion, lead water, as well as homeopathic medicines, the analysis of which is not possible to carry out in a drug store, is carried out in the presence of (under the control of) a pharmacist-analyst.

Chapter 9. Control during release

37. All pharmaceuticals manufactured in drug stores, including homeopathic ones, are subject to control during release.

Control during release includes checking of compliance with:

1) packaging of medicinal products with the physical and chemical properties of the medicinal substances included in them;

2) the doses indicated in the prescription, including the highest single doses, the highest daily doses of drugs to the age of the patient;

3) prescription and label numbers;

4) the patient's surname on the receipt, the surname on the label and on the prescription;

5) registration of medicinal products in accordance with the requirements established by the legislation of the Republic of Kazakhstan in the field of circulation of medicinal products, medical devices.

38. Medicinal products released to medical organizations are issued with inscriptions on solutions for medicinal enemas - "For enemas", on solutions for disinfection - "For disinfection", "Handle with caution", on all medicinal products released to children's departments - "Infant".

39. The person in charge of releasing the medicinal product signs on the back of the prescription (requirements).

10. Control over the quality of manufactured medicinal products

40. Drug stores, in order to control the quality of manufactured medicinal products, quarterly send samples of medicinal products to testing laboratories accredited in the system of technical regulation (hereinafter referred to as the testing laboratory).

41. The testing laboratory conducts tests of manufactured medicines on the basis of an agreement concluded with drug stores in accordance with the Civil Code of the Republic of Kazakhstan dated December 27, 1994.

42. The testing laboratory sends the results of analyzes of manufactured medicinal products to the state body in the field of circulation of medicinal products and medical devices and a drug store.

Appendix 1
to the Rules for intra-
pharmaceutical control of
manufactured medicinal products

List of standard sets of measuring instruments, test equipment, laboratory glassware, auxiliary materials used in analytical works in drug stores

1. Standard set of measuring instruments, test equipment

1. Equal-arm hand scales with weighing limits in grams:

from 0.02 grams to 1 gram;

from 0.1 grams to 5 grams;

from 1 gram to 20 grams;

from 5 grams to 100 grams.

2. Technical pharmacy scales VA-4.

3. Technical weights of the fourth class from 10 mg to 1 kg.

4. Technical weights of the second class, milligram (weights).

5. pH meter (or ionomer).

6. Refractometer.

7. Laboratory mercury glass thermometer at 1 ° C 0 ° C to 100 ° C.

8. Technical thermometer for drying cabinet from 0 oC to 200 oC.

9. Hydrometers (or densimeters).

10. Glass alcohol meters (set).

11. Device for monitoring sterile solutions for the absence of particulate matters (UK-2).

12. Laboratory water bath with fire or electric heating.

13. Laboratory electric stove.

14. Alcohol lamp.

15. Manual tenfold magnifier.

16. Electric drying cabinet.

17. Sandglass table clock for 1, 2, 3, 5 minutes or alarm clock.

18. Indicators and reagents.

2. An indicative list of laboratory glassware, auxiliary materials

1. Straight burette with a tap (or with an olive) with a capacity of 10 milliliters, 25 milliliters (hereinafter - ml).

2. Separating funnel, cylindrical capacity: 50 ml; 100 ml.

3. Glass or porcelain board for drop analysis.

4. Funnel simple conical with a short stem No. 1 D 25 mm; No. 2 D 35 mm.

5. Dropper for indicators and reagents.

6. Glass beakers with a capacity of 50 ml (graduation 5 ml); 100 ml (graduation 10 ml); 500 ml (graduation 25 ml).

7. Microburettes with a capacity of: 3 ml (graduation 0.02 ml); 5 ml (graduation 0.02 ml).

8. Glass rods, D 3 mm.

9. Pharmacy pipette with outlet tube, capacity: 3 ml; 6 ml.

10. Eye pipette.

11. Pipette (Mora) with one mark, capacity: 5 ml; 10 ml; 20 ml; 25 ml.

12. Pipette with graduations, capacity: 1 ml (graduation 0.01 ml); 2 ml (graduation 0.02 ml); 5 ml (graduation 0.05 ml); 10 ml (graduation 0.1 ml).

13. Chemical test tubes with a diameter of 14 mm; 16 mm; 21 mm.

14. Test tubes graduated, capacity: 5 ml; 10 ml; 15 ml; 20 ml.

15. Glasses high and low made of heat-resistant glass, capacity: 50 ml; 100 ml; 250 ml; 400 ml.

16. Slides with cavities (for drop analysis).

17. Mortar and pestle 3, diameter 86 mm.

18. Calcium chloride tubes with one ball: diameter 25 mm; diameter 30 mm.

19. Measuring cylinders with a spout, capacity: 5 ml; 10 ml; 25 ml; 50 ml; 100 ml; 250 ml ; 500 ml

20. Measuring cylinders with a ground stopper, capacity: 10 ml; 25 ml; 50 ml; 100 ml; 250 ml; 500 ml

21. Porcelain evaporating cup No. 1-3, capacity: 25 ml; 50 ml; 100 ml.

22. A jar with a ground-in stopper, with a capacity of 25 ml; 50 ml; 100 ml.

23. Petri dish D 100 mm.

24. Filter paper.

25. Rubber bulb for microburettes and pipettes.

26. Clamps for rubber tubes (screw Hoffmann or spring Mora).

27. Plastic capsule 1 (small), 2 (medium), 3 (large).

28. A pencil on glass, a graphite stick (made of solid graphite, a simple pencil, which is calcined before use).

29. Scissors, tweezers.

30. Polyethylene rack for 10 test tubes, 20 test tubes.

31. Spatula made of polymeric materials or porcelain.

Appendix 2
to the Rules for intra-
pharmaceutical control of
manufactured medicinal products

Form

Log of registration of the results of organoleptic, selective physical control, chemical control of intra-pharmaceutical stock, medicinal products made according to prescriptions (requirements of medical organizations), concentrates, semi-finished products, triturations, ethyl alcohol and packaging

Control date	№ (number of analyses)	№ of prescription or requirements of a medical organization indicating the department	№ of batch of intra-pharmaceutical stock (for packing, the batch number or analysis number of the manufacturer's enterprise or testing laboratory is indicated)	Composition of the medicinal product or analyte (ion). Conventional designation for individually manufactured drugs (for children - "D"; in eye practice - "Gl". The content of narcotic drugs, psychotropic, toxic substances and precursors is underlined in red pencil)	Results of selective physical, organoleptic control (organoleptic control is considered as a physical control check)
1	2	3	4	5	6

Continuation of the table

Results of quality control (determination of authenticity) "+" or "-"	Full chemical control results (calculation formulas, density, refractive index, etc.)	Surname of manufacturer , packer	Verifier's signature	Medicinal product quality assessment	
				Satisfactory	Unsatisfactory (underlined in red pencil)
7	8	9	10	11	12

Appendix 3
to the Rules for intra-pharmaceutical control of manufactured medicinal products

Form

Log of registration of the results of control of medicinal substances for authenticity

Date of filling and control	№ (№ of analyses)	Name	№ of batch of medicinal substances or No. of analysis of test laboratory	№ of the filled pharmacy tare	The analyte (ion)	Assessment of the quality of medicinal substances ("corresponds ", "does not correspond")	Signature of the person who filled in	Verifier's signature
1	2	3	4	5	6	7	8	9

Appendix 4
to the Rules for intra-pharmaceutical control of manufactured medicinal products

Form

Log of registration of the results of control of purified water and water for injection

Date of receipt (distillation of water)	Date of control	№ (№ of analyses)	№ of cylinder	Results of control for absence of particulate matters: (the absence of particulate matters is marked with a "-" sign)		
				Chloride Ion	Sulfate ion	Calcium salts
1	2	3	4	5	6	7

Continuation of the table

Results of control for absence of particulate matters: (the absence of particulate matters is marked with a "-" sign)			Assessment of the quality of purified water and water for injection		Verifier's signature
Ammonium salts	Reducing substances	Carbon dioxide	Satisfactory	Unsatisfactory	
8	9	10	11	12	13