

***The Order of the Ministry of Healthcare of the Russian Federation No. 388 as of 01.11.2001 “On State Quality Standards of Medicines” (registered with the Russian Ministry of Justice No. 3041 as of 16.11.2001) approved the Industry Standard 91500.05.001-00 “Quality Standards of Medicines. Basic Provisions”, which regulates the procedures of development, execution, expert evaluation, agreement, approval, designation, and registration of state quality standards of medicines and the procedure of introduction of amendments to them.  
The Industry Standard is given below.***

Annex

APPROVED

Order of the Ministry of Healthcare of the Russian Federation No. 388 as of 01.11.2001

**INDUSTRY STANDARD.  
QUALITY STANDARDS OF MEDICINES.  
BASIC PROVISIONS**

**OST 91500.05.001-00**

**I. General provisions**

1.1. The Industry Standard 91500.05.001-00 “Quality Standards of Medicines. Basic Provisions” (hereinafter the “OST”) was developed in accordance with the Law of the Russian Federation No. 5154-1 as of 10.06.93 “On Standardization”, Federal Law No. 86-FZ as of 22.06.98 “On Medicines”, and Statute of the Ministry of Healthcare of the Russian Federation, approved by the Decree of the Government of the Russian Federation No. 659 as of 03.06.97 (amended and revised).

1.2. This OST establishes the procedures of development, execution, expert evaluation, agreement, approval, designation, registration of, and introduction of amendments to state quality standards of medicines.

1.3. This OST does not apply to:

- blood and its components used in transfusiology;
- raw materials of animal origin used exclusively for preparation of products subject to further processing for preparation of medicines;
- medicines made in pharmacy institutions.

## II. Terms and definitions

The following terms with the corresponding definitions are used for the purpose of this OST:

**excipients:** substances of organic or inorganic nature that are used in manufacture of finished pharmaceutical forms to impart the desired properties to them. The list of excipients is extensive; depending on the type of pharmaceutical form, they may include thickening agents, surface and buffer, corrigents, preservatives, stabilizers, fillers, leavening agents, glidants, etc.;

**homeopathic medicines:** single- or multicomponent products that normally contain microdoses of active compounds, manufactured through a special procedure and intended for oral, injection, or topical administration in various pharmaceutical forms;

**state reference standard:** a reference standard, the quality parameters of which are regulated by the duly approved monograph. Working reference standards of medicinal substances can be used in analysis of finished pharmaceutical forms;

**state pharmacopoeia:** a collection of monographs\*;

**making of medicines:** making of medicines in a pharmacy institution that holds a license for pharmaceutical activity according to the rules of making medicines approved by the federal authority for quality control of medicines;

**immunobiological medicines:** medicines intended for immunologic prophylaxis and immunologic therapy\*;

**blood components:** blood cells, corpuscles, and plasma, obtained from blood and intended for administration to a recipient;

**blood:** a liquid obtained from a human donor, which consists of cellular elements and plasma and is used after a due inspection for obtaining separate components and administration to a recipient.

**medicines:** substances used for prevention, diagnostics, and treatment of diseases and pregnancy prevention, obtained from blood and plasma, as well as

organs and tissues of humans or animals, plants, minerals, via synthesis or with the aid of biological technologies. Medicines also include substances of plant, animal, or synthetic origin that exhibit pharmacological activity and are intended for manufacture and making of medicines\*;

**medicinal products:** dosed medicines in a specific pharmaceutical form;

**pharmaceutical form:** a state, convenient for usage, imparted to a medicine or medicinal plant raw materials for achieving the desired therapeutic effect (the definitions of pharmaceutical forms that can be used in preparation of state quality standards of medicines are given in Annex 1 to this OST);

**international nonproprietary name (INN):** name of a medicine approved by the World Health Organization (WHO);

**circulation of medicines:** a general concept of activities that include development, studies, manufacture, making of, storage, packaging, transportation, state registration, standardization and quality control, selling, labeling, advertising, use of medicines, disposal of medicines that became unfit for use or medicines past their expiry date, and other activities in the sphere of circulation of medicines\*;

**developer of a medicine:** an organization that holds patent rights to a medicine and the copyright on the results of its preclinical studies\*;

**manufacturer of medicines:** an organization that manufactures medicines in accordance with the requirements of this Federal Law\*;

**blood products:** medicinal products obtained from human blood and released in liquid, dry, and frozen form;

**proprietary medicines:** medicines, rights to manufacture and selling of which are protected by the patent legislation of the Russian Federation\*;

**working reference standard:** a sample of a batch substance that meets the requirements of the corresponding quality standard of medicines;

**batch:** a certain amount of a medicine obtained as a result of one manufacturing cycle. The main requirement to a batch is its uniformity.

**reference standards:** substances used for quality control of medicines that are compared against the tested medicines in analyzing the latter through physicochemical and biological methods. Reference standards are divided into chemical and biological for convenience; one and the same reference standard can be used for physicochemical as well as biological analyses in accordance with the directions of a monograph;

**shelf life:** a period of time, within which a medicine should fully satisfy all the requirements of the corresponding state quality standard of a medicine;

**substance:** a substance of plant, animal, microbial, or synthetic origin that exhibits pharmacological activity and is intended for manufacture and making of medicines;

**monograph:** a state quality standard of a medicine that contains the list of quality tests and control methods for a medicine\*.

### III. Preparation procedure for state quality standards of medicines

3.1. The following types of state quality standards of medicines are developed and approved:

- 1) general monograph (OFS);
- 2) monograph (FS);
- 3) in-house monograph (FSP).

3.2. State quality standards of medicines should ensure the development of a quality, effective, and safe medicine.

3.3. State quality standards of medicines should be revised in a timely manner considering the recent medical, pharmaceutical, and other scientific achievements, provisions of the leading foreign pharmacopoeias, and recommendations of the leading international organizations in the sphere of pharmaceuticals.

3.4. A general monograph includes the list of tests or testing methods for a specific pharmaceutical form, description of physical, physicochemical, chemical, biochemical, biological, and microbiological methods of analysis of medicines, and requirements to reagents, titrated solutions, and indicators used.

3.5. A monograph is developed for a medicine under an international nonproprietary name if available (for monocomponent medicines) and contains the list of mandatory tests and quality control methods (considering its pharmaceutical form), corresponding to the provisions of the leading foreign pharmacopoeias.

3.6. The development of a monograph for an original (proprietary) medicine during the term of patent protection and its inclusion into the State Pharmacopoeia is only possible by agreement with the developer of a medicine or after the term of the patent has expired.

3.7. General monographs and monographs constitute the State Pharmacopoeia.

3.8. The State Pharmacopoeia is published by the Russian Health Ministry and is subject to republication every 5 years.

3.9. An in-house monograph contains the list of tests and quality control methods for a medicine, manufactured by a specific manufacturer and is developed in view of the requirements of the State Pharmacopoeia and this standard.

Quality requirements for medicines, contained in an FSP, should not be lower than the requirements stated in the State Pharmacopoeia, in view of the requirements of this standard.

3.10. The effective period of an FSP is established taking into account the level of manufacturing process of the specific manufacturer of a medicine, but must not exceed 5 years.

3.11. When developing a new medicine, an FSP for the substance used in its manufacture is developed simultaneously with an FSP for said medicine, in the case of absence of a state quality standard of a medicine for the substance.

When developing a new immunobiological medicine, an FSP for the substance used in its manufacture is developed if necessary.

3.12. General monographs and monographs for reference standards are developed by an organization authorized by the Russian Ministry of Health.

#### **IV. Procedure of arrangement and presentation of state quality standards of medicines**

4.1. The title of a state quality standard of a medicine gives the name of the medicine.

4.2. The list of the principal sections of an FS and an FSP and the order of their presentation, considering specific pharmaceutical forms, is given in Annex 2 to this OST.

4.3. All quality tests contained in an FSP should be presented in form of a summary table (specification). The specification is a mandatory part of an FSP.

4.4. The order of arrangement of state quality standards of medicines for substances, medicines, and medicinal plant raw materials is given in Annexes 3-5 to this OST.

4.5. Title pages of an OFS, FS, or FSP should be arranged in accordance with Annexes 6, 7, and 8 to this OST.

The last page of an FSP should be arranged in accordance with Annex 9 to this OST.

4.6. Sections of an OFS, FS, or FSP are not numbered.

4.7. The presentation of the text should be concise, contain no repetitions, and exclude the possibility of different interpretations.

4.8. The abbreviation of words in the text and inscriptions under figures, schemes, and other illustrations is not permitted, excluding abbreviations used in the legislation of the Russian Federation.

4.9. Quality requirements to medicines in the text part of standards are presented in form of imperative.

When presenting the mandatory requirements, limits, and methods, such words as “shall”, “should”, “required” and their derivatives are used.

4.10. Section titles start a new paragraph and are set off in boldface font or underlined.

4.11. If the requirements, limits, methods, etc. applying to a medicine are established in the State Pharmacopoeia or other state or industry standard, references to the sources should be given instead of repeating their text.

4.12. The presentation of the text on the substance used in manufacture of a medicine should be accompanied by a reference to the regulatory document, according to which it is manufactured.

4.13. If the text of an OFS, FS, or FSP contains references to reagents, auxiliary materials, etc. that are manufactured in accordance with other regulatory documents, the designation of such documents should be given.

## **V. Procedure of submittal of state quality standards of medicines for expert evaluation, agreement, and approval**

5.1. A draft state quality standard of a medicine, signed by its Developer, is submitted together with the following documents:

- cover letter;
- explanatory note;
- tabulated analytical data confirming the numeric values given in the draft state quality standard of a medicine for at least 5 batches of samples (3 batches of samples for immunobiological medicines);
- tabulated analytical data confirming the shelf life of the product, in accordance with the requirements of the corresponding industry standard;

- draft instruction for use of a medicine (for a new medicine or a generic medicine, for which a state quality standard of a medicine is developed for the first time);
- tabulated comparison of tests provided by the draft state quality standard of a medicine against the same tests given in national and foreign pharmacopoeias if available;
- product sample in a labeled package;
- certificate of metrological guarantee of quality control of a medicine.

5.2. An explanatory note to the draft state quality standard of a medicine should contain the following information:

- name of Manufacturer (Developer) of the medicine;
- brief description of synthesis or manufacturing procedure of the product;
- detailed justification of the investigation methods, tests, and limits, given in the draft, and also the description of other methods that were used to analyze the given medicine or substance;
- number of samples and manufacturing documents used in development of the draft state quality standard of a medicine;
- detailed justification of deviations from the general requirements of the State Pharmacopoeia, if any;
- foreign pharmacopoeias and other sources that describe a similar medicine with the data on the quality compared to foreign medicines; if a medicine is new or original, this fact should be mentioned.

5.3. An explanatory notes and tabulated analysis results are signed by the Manager of the Manufacturer (Developer) of the medicine or by a person authorized by them.

5.4. An expert evaluation of the draft quality standard of medicines and its agreement are performed by organizations authorized by the Russian Ministry of Health.

If necessary, the Russian Ministry of Health can involve core organizations into experimental testing of the state quality standard of a medicine by agreement with the Manufacturer.

5.5. An expert evaluation investigates the scientific and technical level of the draft state quality standard of a medicine and its compliance with the current requirements to regulatory documents for medicines, including the following:

- correspondence of quality tests and limits of a medicine and its consumer package to the requirements of the State Pharmacopoeia;
- justification of the list of tests and optimality of quality limits and shelf life of a medicine;
- accuracy and unambiguousness of the terms, definitions, chemical nomenclature, and physical units used.

5.6. Individuals involved into the expert evaluation and approval of in-house monographs should ensure confidentiality of the information obtained through this work.

5.7. The organization, authorized by the Russian Ministry of Health for conducting the expert evaluation of a state quality standard of a medicine, sends the documents to the Russian Ministry of Health for approval following the expert evaluation.

## **VI. Procedure of designation and registration of state quality standards of medicines**

6.1. Following the approval, an OFS, FS, or FSP is registered with the organization authorized by the Russian Ministry of Health and designated.

6.2. A designation of an OFS and FS should consist of an abbreviated name of the type of state quality standard of a medicine, code of the Russian Ministry of Health, registration number assigned to the document, and the last two digits of the year of approval or revision, separated by dashes.

Example: OFS or FS 42-00001-00, where

OFS or FS: abbreviated name of the category of quality standard of a medicine;

42: code assigned to the Russian Ministry of Health for designation of documents on standardization;

00001: registration number of the document;

00: last two digits of the year of approval of the document (00 for 2000, 01 for 2001, 02 for 2002, etc.).

6.3. A designation of an FSP should consist of the abbreviated name of the type of state quality standard of a medicine, code of the Russian Ministry of Health, code of the enterprise, registration number of the document, and the last two digits of the year of approval of the standard, separated by dashes.

Example: FSP 42-0001-00001-00, where

FSP: abbreviated name of the type of state quality standard of a medicine;

42: code assigned to the Russian Ministry of Health for designation of documents on standardization;

0001: four-digit code of the enterprise;

00001: registration number of the document;

00: last two digits of the year of approval of the document.

6.4. Registration numbers are assigned sequentially starting from 00001.

6.5. Codes of enterprises are made up from four digits starting from 0001.

A code of enterprise is assigned to the Manufacturer or the Developer of medicines upon submittal the first FSP for approval.

## **VII. Procedure of introduction of amendments to state quality standards of medicines**

7.1. Amendments are introduced into state quality standards of medicines when the higher scientific and technological level makes it possible to improve the quality of a medicine or to make the quality tests more precise. The amendments introduced must not result in the quality degradation of medicines.

7.2. The first page of an amendment to a quality standard of a medicine is executed in the form given in Annex 10.

7.3. Texts of the old and the new versions of sections (subsections or paragraphs) are given in full.

The expert evaluation and approval of the amendments introduced into state quality standards of medicines are performed according to the procedure established for the expert evaluation and approval of state quality standards of medicines.

\* Article 4 of the Federal Law "On Medicines"

Annex 1

to the Industry Standard OST 91500.05.001-00 "Quality Standards of Medicines. Basic Provisions"

## Pharmaceutical forms. Terms and definitions

**Aerosols:** a pharmaceutical form that is presented as solutions, emulsions, and suspensions of pharmaceutical substances, pressurized with propellants in a tightly sealed container equipped with a spray valve (metering or non-metering).

An aerosol where the contents of a container are released with the help of air is called a spray.

Aerosols are intended for inhalation. A type of inhalation is powders for inhalation (inhalers) that can be supplied in special metering devices such as rotadisks, ventodisks, etc.

Aerosols may also be intended for application of a medication on the skin, mucous membranes, and wounds.

**Cakes:** solid single-dose pharmaceutical form obtained through pressing of comminuted medicinal plant raw materials or a mixture of various types of plant raw materials without excipients, intended for the preparation of infusions and decoctions.

**Granules:** solid single-dose or multi-dose pharmaceutical form for oral administration consisting of spherical or irregular aggregates (grains) that contain a mixture of active ingredients and excipients.

Granules may be coated, including gastro-resistant; uncoated; effervescent; for the preparation of oral solutions and with modified release of active ingredients. A multi-dose package with granules may be equipped with a metering device.

**Pills:** solid single-dose pharmaceutical form obtained through layering active ingredients on microparticles of inert carriers with the aid of sugar syrups.

**Drops:** liquid pharmaceutical form containing one or more active ingredients, dissolved, suspended, or emulsified in a suitable solvent and metered in drops.

Two types of drops may be distinguished: for oral use and for external use.

**Capsules:** single-dose pharmaceutical form, which consists of a hard or soft gelatin shell containing one or more active ingredients with or without excipients.

Capsules can be divided into: hard, soft, microcapsules, gastro-resistant, and pellets.

**gastro-resistant:** capsules that release their active ingredient in the intestinal fluid.

**microcapsules:** capsules that consist of a thin shell, made of polymer or other material, are spherical or irregular in shape and 1 to 2,000  $\mu\text{m}$  in size, and contain solid or liquid active ingredients with or without excipients.

**soft:** single-part capsules of various shapes (spherical, oviform, oblong, etc.) with liquid or paste-like substances.

**hard:** cylindrical capsules with hemispherical ends that consist of two parts inserted one into the other without gaps. Capsules may be filled with powders, granules, microcapsules, pellets, and tablets.

**Pellets:** coated solid spherical particles that contain one or more active ingredients with or without excipients and are 2,000 to 5,000  $\mu\text{m}$  in size.

**Pharmaceutical forms for injections:** sterile pharmaceutical forms for parenteral use presented as solutions, suspensions, and emulsions, and also as solid pharmaceutical substances (powders, tablets, porous masses) that are dissolved in a sterile solvent immediately before administration. Injections may be of small volume (up to 100 ml) and of large volume (100 ml and more) (infusions).

**powders for injections:** sterile solid medicines used for the preparation of solutions or suspensions for injections.

**solutions for injections:** sterile aqueous or non-aqueous solutions of pharmaceutical substances in a suitable solvent.

**suspensions for injections:** sterile finely dispersed suspensions.

**emulsions for injections:** sterile finely dispersed emulsions.

**Ointments:** soft pharmaceutical form intended for application on the skin, mucous membranes, and wounds, which consists of a basis and pharmaceutical substances homogeneously dispersed in it.

By the type of disperse system, ointments can be divided into: homogeneous (alloys and solutions), suspension, emulsion, and combination; depending on their consistency: ointments proper, creams, gels, liniments, and pastes.

**gels:** viscous ointments that are able to hold their shape and are elastic and plastic.

By the type of disperse system, hydrophilic and hydrophobic gels are distinguished.

**creams:** soft ointments that are oil-in-water or water-in-oil emulsions.

**liniments:** ointments presented as viscous liquids.

**pastes:** thick ointments with the content of powder-like substances exceeding 25%.

**Tinctures:** liquid pharmaceutical form presented as alcoholic and aqueous-alcoholic extractions from medicinal plant raw materials, obtained without heating and removal of the extract.

**Solutions:** liquid pharmaceutical form obtained by dissolving liquid, solid, or gaseous substances in a suitable solvent.

Solutions are used orally and externally, and also for injections.

**Medicinal plant mixtures:** mixtures of several types of comminuted (rarely whole) medicinal plant raw materials, sometimes with the addition of salts and essential oils.

**Syrups:** liquid pharmaceutical form for oral use presented as a concentrated solution of various sugars, and also their mixture with pharmaceutical substances.

**Suppositories:** solid single-dose pharmaceutical form that consists of a basis and pharmaceutical substances and melts (dissolves, disintegrates) at body temperature.

Suppositories are intended for rectal (suppositories), vaginal (pessaries and balls) and other routes of administration (sticks).

**Suspensions:** liquid pharmaceutical form that is a disperse system containing one or more solid pharmaceutical substances suspended in a suitable liquid.

Suspensions are used orally and externally, and also for injections.

**Tablets:** solid single-dose pharmaceutical form obtained by compressing powders and granules that contain one or more pharmaceutical substances with or without excipients.

Tablets can be divided into: uncoated, effervescent, coated, gastro-resistant, modified-release, and for use in the mouth.

**gastro-resistant:** tablets that resist the gastric fluid and release their pharmaceutical substance or substances in the intestinal fluid.

They are prepared by covering tablets with a gastro-resistant coating (enteric-coated tablets), or by compressing granules and particles already covered with gastro-resistant coating, or by compressing pharmaceutical substances together with a gastro-resistant filler (durules).

**uncoated:** single-layer or multi-layer tablets obtained by single or successive compression. In multi-layer tablets, each layer may contain different pharmaceutical substances.

**coated:** tablets covered with one or more layers of various substances, such as natural and synthetic materials and carbohydrates, with the possible addition of

surfactants. Thin coating (less than 10% of a tablet mass) is usually called film coating.

Sugar coating, which contains one or more pharmaceutical substances and is layered on microparticles of inert carriers, makes it possible to prepare a pharmaceutical form called pills.

**effervescent:** uncoated tablets usually containing acid substances and carbonates or hydrogen carbonates, which react rapidly in the presence of water to release carbon dioxide; they are intended to be dissolved or dispersed in water immediately before administration.

**for use in the mouth:** usually uncoated tablets prepared by a special procedure to effect a release of a pharmaceutical substance or substances in the oral cavity for topical or systemic absorption (buccal tablets, sublingual tablets, etc.).

**modified-release:** coated or uncoated tablets that contain special excipients or are prepared by special procedures, designed to modify the rate and the place at which pharmaceutical substance is released.

**Extracts:** concentrated extractions from medicinal plant or animal raw materials presented as mobile, viscous liquids or dry masses. Extracts are divided into: liquid extracts (mobile liquids); soft extracts (viscous masses with the moisture content not more than 25%); dry extracts (loose masses with the moisture content not more than 5%).

**Elixirs:** liquid pharmaceutical form presented as a clear mixture of aqueous-alcoholic extractions from medicinal plant raw materials with the addition of pharmaceutical substances, sugars, and flavoring agents.

**Emulsions:** liquid pharmaceutical form that is a disperse system containing two or more mutually insoluble or immiscible liquids, one of which is emulsified in the other.

Emulsions are used orally and externally, and also for injections.

### **Principal groups of medical immunobiological medicines**

**Allergens and allergoids:** substances of antigenic or haptenic nature used for hyposensibilization and allergy diagnostics.

**Anatoxins:** bacterial exotoxins that have lost their toxicity as a result of inactivation (e.g. with formalin), but retain their antigenic properties.

**Bacteriophages:** viruses capable of penetrating into a bacterial cell, replicating within it, causing its lysis or transition to lysogeny (phage carriage).

**Vaccines:** medicines obtained from live attenuated strains or killed microbial cultures or their antigens and intended for active immunization.

**Diagnostic immunobiological medicines:** medicines intended for diagnostics of infectious diseases.

**Immunoglobulins (antibodies):** immunologically active protein fraction of human or animal blood serum (plasma) that contains antimicrobial and/or antitoxic antibodies.

**Immunomodulators:** substances that modify an immune response of the body, including cytokines, interferons, etc.

**Probiotics:** bacteria that are apathogenic for humans and exhibit antagonistic activity against pathogenic and opportunistic bacteria, facilitating the restoration of normal microflora.

**Heterologous serums:** blood serums obtained from the animals immunized with this or that antigen that contain corresponding antibodies.

Annex 2

to the Industry Standard OST 91500.05.001-00 “Quality Standards of Medicines. Basic Provisions”

## **List of sections in monographs and in-house monographs**

### **Pharmaceutical substance**

1. Product name in Russian
2. International nonproprietary name (INN) in Russian
3. Chemical name in accordance with the IUPAC requirements
4. Structural and empirical formulae and molecular mass
5. Content of the active ingredient (in percent or units)
6. Description
7. Solubility
8. Identification

9. Melting (decomposition) point, or freezing point, or boiling point
10. Density
11. Specific rotation
12. Specific absorbance
13. Refractive index
14. Clarity of solution
15. Colority of solution
16. pH, or acidity, or alkalinity
17. Particulate contamination
18. Impurities (related substances)
19. Purity tests (chlorides, sulfates, sulfated ash, heavy metals, etc.)
20. Loss on drying, or water via Karl Fischer titration
21. Residual solvents (if used at the final stage of the manufacturing process)
22. Pyrogens, or bacterial endotoxins (LAL test)
23. Toxicity
24. Histamine-like substances
25. Microbiological purity, or sterility
26. Assay
27. Packaging
28. Labeling
29. Transportation
30. Storage
31. Shelf life
32. Pharmacological group
33. Special precautions

Note. Sections 1, 3-8, 18, 20, 25-32 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance, manufacturing procedures, and pharmaceutical forms that will be prepared from this substance.

#### **I. Pharmaceutical forms for injections (solutions for injections)**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description

5. Identification
6. Clarity
7. Colority
8. pH, or acidity, or alkalinity
9. Particulate contamination
10. Density
11. Viscosity
12. Impurities (related substances)
13. Nominal volume
14. Pyrogens, or bacterial endotoxins (LAL test)
15. Toxicity
16. Histamine-like substances
17. Sterility
18. Assay
19. Packaging
20. Labeling
21. Transportation
22. Storage
23. Shelf life
24. Pharmacological group
25. Special precautions

Note. Sections 1-6, 9, 13, 17-24 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance, preparation procedure of the given pharmaceutical form, and method of its administration.

## **II. Dry pharmaceutical forms for injections (powders for preparation of solutions and suspensions for injections)**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description
5. Identification
6. Average mass and uniformity of mass
7. Clarity

8. Colority
9. pH, or acidity, or alkalinity
10. Particulate contamination
11. Impurities (related substances)
12. Loss on drying, or water
13. Pyrogens, or bacterial endotoxins (LAL test)
14. Toxicity
15. Histamine-like substances
16. Sterility
17. Uniformity of dosage units
18. Assay
19. Packaging
20. Labeling
21. Transportation
22. Storage
23. Shelf life
24. Pharmacological group
25. Special precautions

Note. Sections 1-7, 10, 18-24 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance, preparation procedure of the given pharmaceutical form, and method of its administration. If necessary, the section "Solubility", which specifies the time of complete dissolution when preparing a solution in accordance with the instruction for use, can be included as well.

### **III. Eye drops**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description
5. Identification
6. Clarity
7. Colority
8. pH, or acidity, or alkalinity
9. Particulate contamination

10. Viscosity
11. Osmolality
12. Impurities (related substances)
13. Nominal volume
14. Sterility
15. Assay
16. Packaging
17. Labeling
18. Transportation
19. Storage
20. Shelf life
21. Pharmacological group

Note. Sections 1-6, 8-11, 14-21 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance.

#### **IV. Liquid pharmaceutical forms for oral and external use (solutions, suspensions, syrups, and emulsions)**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description
5. Identification
6. pH, or acidity, or alkalinity
7. Density
8. Viscosity
9. Impurities (related substances)
10. Nominal volume
11. Microbiological purity
12. Assay
13. Packaging
14. Labeling
15. Transportation
16. Storage
17. Shelf life

## 18. Pharmacological group

Note. Sections 1-5, 10-18 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance.

## **V. Aerosols**

1. Product name in Russian
2. INN (for monocomponent medicines) in Russian
3. Composition
4. Description
5. Identification
6. Pressure test
7. Leakage test
8. Valve function test
9. Dosage unit mass
10. Number of discharges per container
11. Delivered amount
12. Particle size
13. Water
14. Impurities (related substances)
15. Microbiological purity
16. Uniformity of dosage units
17. Assay
18. Packaging
19. Labeling
20. Transportation
21. Storage
22. Shelf life
23. Pharmacological group

Note. Sections 1-8, 11, 15, 17-23 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance and dosage.

## **VI. Tablets and pills**

1. Product name in Russian

2. INN in Russian
3. Composition
4. Description
5. Identification
6. Average mass and uniformity of mass
7. Talc, aerosil, titanium dioxide
8. Dissolution, or disintegration
9. Impurities (related substances)
10. Microbiological purity
11. Uniformity of dosage units
12. Assay
13. Packaging
14. Labeling
15. Transportation
16. Storage
17. Shelf life
18. Pharmacological group

Note. Sections 1-6, 8-10, 12-18 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance and dosage. The test "Uniformity of mass" is not performed if the test "Uniformity of dosage units" is included.

## **VII. Capsules (microcapsules)**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description
5. Identification
6. Average mass of the contents and uniformity of mass
7. Dissolution, or disintegration
8. Impurities (related substances)
9. Microbiological purity
10. Uniformity of dosage units
11. Assay
12. Packaging

13. Labeling
14. Transportation
15. Storage
16. Shelf life
17. Pharmacological group

Note. Sections 1-7, 9, 11-17 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance and dosage. The test “Uniformity of mass” is not performed if the test “Uniformity of dosage units” is included.

### **VIII. Suppositories**

1. Product name in Russian
2. INN in Russian
3. Composition
4. Description
5. Identification
6. Average mass and uniformity of mass
7. Melting point, or softening time, or time of dissolution
8. Impurities (related substances)
9. Microbiological purity
10. Uniformity of dosage units
11. Assay
12. Packaging
13. Labeling
14. Transportation
15. Storage
16. Shelf life
17. Pharmacological group

Note. Sections 1-7, 9-16 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance and dosage. The test “Uniformity of mass” is not performed if the test “Uniformity of dosage units” is included.

### **IX. Ointments (creams, gels, liniments, pastes)**

1. Product name in Russian

2. INN in Russian
3. Composition
4. Description
5. Identification
6. Mass of the contents of a container
7. pH of an aqueous solution
8. Particle size
9. Impurities (related substances)
10. Microbiological purity, or sterility
11. Assay
12. Packaging
13. Labeling
14. Transportation
15. Storage
16. Shelf life
17. Pharmacological group

Note. Sections 1-6, 10-17 are mandatory.

The inclusion of other sections depends on the nature of the pharmaceutical substance.

**X. Medicinal plant raw materials and mixtures (packaged products: cakes, bags, filter bags, cut and compressed form, etc.)**

1. Product name in Russian and Latin.
2. Latin and Russian names of the producing plant(s) and their families.
3. Identification test for whole and comminuted raw materials:
  - 3.1. Appearance;
  - 3.2. Microscopy illustrated with a microphotograph or a drawing;
  - 3.3. Qualitative and/or histochemical reactions; chromatographic tests.
4. Quantitative tests for whole and comminuted raw materials:
  - 4.1. Content of pharmacologically active substances or biological activity;
  - 4.2. Loss on drying;
  - 4.3. Total ash;
  - 4.4. Ash insoluble in 10% hydrochloric acid solution;

4.5. Impurities: comminuted (sieve test), discolored pieces of the raw materials, other parts of the plant not subject to harvesting, organic impurity, mineral impurity.

5. Microbiological purity.

6. Packaging of whole and comminuted raw materials (bulk) and packaged products (packs, bags, cakes, cut and compressed form, filter bags, etc.).

7. Labeling of whole and comminuted raw materials and packaged products (packs, bags, cakes, cut and compressed form, filter bags, etc.). Additional indication: "The product has passed the radiological control according to SanPiN 2.3.2560-96"

8. Storage

9. Shelf life

10. Pharmacological group.

Note. The quality evaluation of packaged products in cakes and cut and compressed form includes the additional disintegration and uniformity of mass tests.

## **XI. Tinctures and elixirs**

1. Product name in Russian

2. INN in Russian

3. Composition

4. Description

5. Identification

6. Heavy metals

7. Assay

8. Alcohol content, or density

9. Dry residue

10. Nominal volume

11. Microbiological purity, or sterility

12. Packaging, labeling, storage

13. Shelf life

14. Pharmacological group

## **XII. Extracts (liquid, soft, dry)**

1. Product name in Russian

2. INN (for monocomponent medicines) in Russian
3. Composition
4. Description
5. Identification
6. Heavy metals
7. Assay
8. Alcohol content, or density (for liquid extracts)
9. Dry residue
10. Loss on drying (for soft and dry extracts)
11. Nominal volume
12. Average mass (for single-dose extracts)
13. Granulometric composition (for dry extracts)
14. Microbiological purity
15. Packaging, labeling, storage
16. Shelf life
17. Pharmacological group.

### **XIII. Homeopathic products**

#### **Pharmaceutical forms for injections**

1. Product name in Russian
2. Composition with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients and preservatives
3. Description
4. Identification test
5. Colority (evaluation method and standard)
6. Clarity (evaluation method and standard)
7. Particle size (for suspensions and emulsions)
8. Solution pH
9. Nominal volume determination
10. Particulate contamination test
11. Pyrogen test (test dose) (if necessary)
12. Sterility
13. Assay
14. Packaging, labeling, storage

15. Shelf life
16. Pharmacological activity (for complex products only)

### **Liquid pharmaceutical forms for oral and external use**

1. Product name in Russian
2. Composition with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients and preservatives
3. Description (appearance, color)
4. Identification test
5. pH (if necessary)
6. Density
7. Viscosity
8. Particle size (for suspensions and emulsions)
9. Nominal volume determination
10. Alcohol content (for alcohol-containing products)
11. Assay
12. Microbiological purity
13. Packaging, labeling, storage
14. Shelf life
15. Pharmacological activity (for complex products only)

### **Suppositories**

1. Product name in Russian
2. Composition per suppository with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients
3. Description
4. Average mass of a suppository, variation limits
5. Identification test
6. Melting point, or softening time, or time of dissolution
7. Homogeneity test
8. Assay
9. Microbiological purity
10. Packaging, labeling, storage
11. Shelf life
12. Pharmacological activity (for complex products only)

**Ointments**

1. Product name in Russian
2. Composition with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients
3. Description
4. Identification test
5. Mass of the contents of a container
6. pH of an aqueous solution (if necessary)
7. Homogeneity test, or particle size
8. Assay
9. Microbiological purity
10. Packaging, labeling, storage
11. Shelf life
12. Pharmacological activity (for complex products only)

**Tablets and pills**

1. Product name in Russian
2. Composition per tablet with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients and fillers
3. Description
4. Average mass of tablets, and mass variation
5. Identification test
6. Disintegration
7. Assay
8. Microbiological purity
9. Packaging, labeling, storage
10. Shelf life
11. Pharmacological activity (for complex products only)

**Granules (grains)**

1. Product name in Russian
2. Composition per granule with the indication of homeopathic dilutions of the components and their amounts, as well as all excipients
3. Identification test

4. Description
5. Number of pieces in 2 g
6. Disintegration
7. Mass of the contents of a container and mass variation
8. Loss on drying
9. Microbiological purity
10. Assay
11. Packaging, labeling, storage
12. Shelf life
13. Pharmacological activity (for complex products only)

Note. The necessity of introducing the sections "Identification" and "Assay" for homeopathic products is determined individually depending on the composition of the product and the limit of detection of its components

**XIV. Immunobiological medicines (allergens, allergoids, anatoxins, bacteriophages, vaccines, immunoglobulins (antibodies), Immunomodulators, and diagnostic products)**

**Vaccines and anatoxins**

1. Introductory part
2. Description
3. Identification
4. Solubility (for dry products); disintegration (for tablets)
5. Clarity
6. Colority
7. Absence of particulate contamination (for products administered parenterally)
8. pH
9. <sup>\*</sup>Loss on drying
10. Vacuum (shielding gas, hermetization)
11. <sup>\*</sup>Chemical tests (protein; total protein nitrogen; nucleic acids; polysaccharides, etc.)
12. Sterility (absence of foreign microorganisms and fungi for live vaccines)
13. Microbiological purity (for non-injection forms)
14. <sup>\*</sup>Pyrogens or bacterial endotoxins
15. Toxicity

- 16.<\*>Specific safety
17. Specific activity (immunogenicity)
- 18.<\*>Antigenic activity
19. Completeness of absorption (for absorbed products)
- 20.<\*>Thermostability
21. Impurities
22. Master strains
23. Adjuvants
- 24.<\*>Antibiotic content
25. Solvents included with the product
26. Packaging, labeling, transportation, storage
27. Shelf life
28. Intended use

### **Human immunoglobulins**

1. Introductory part
2. Description
3. Identification
4. Solubility (for dry products)
5. Clarity
6. Colority
7. Absence of particulate contamination
8. pH
9. Loss on drying
10. Vacuum (shielding gas, hermetization)
11. Protein
12. Electrophoretic homogeneity
13. Molecular parameters
14. Fractional composition
15. Thermostability (for liquid products)
16. Sterility
17. Pyrogens, or bacterial endotoxins
18. Toxicity
19. Specific activity (for specific antiviral, antibacterial, or antitoxic Ig: antibody content expressed in IU, titers, etc.; for products enriched with immunoglobulins of

A or M classes: their quantitative content; for antiallergic products: antiallergic activity, etc. depending on the product)

20. Specific safety:

- a. HBsAg and antibodies to HIV-1 and HIV-2 absence tests (other human blood contaminants in case of determined necessity) (all products);
- b. anticomplementarity (for Ig intended for intravenous administration);
- c. hypotensive activity (for histaglobulin, histaserotoglobulin, etc.).

21. Packaging, labeling, transportation, storage

22. Shelf life

23. Intended use

### **Heterologous serums**

1. Introductory part

2. Description

3. Identification

4. <sup>\*</sup>Solubility (for dry products)

5. Clarity

6. Colority

7. Absence of particulate contamination

8. pH

9. Loss on drying (for dry products)

10. Vacuum (hermetization)

11. Protein

12. Sterility

13. Pyrogens or bacterial endotoxins

14. Toxicity

15. Specific activity

16. Potency

17. Adjuvants

18. <sup>\*</sup>Solvents included with the product

19. Packaging, labeling, transportation, storage

20. Shelf life

21. Intended use

### **Bacteriophages**

1. Introductory part
2. Description
3. Identification
4. Average mass (for tablets and suppositories)
5. Disintegration (for tablets). Dissolution (for suppositories)
6. Sterility, or microbiological purity (for tablets, suppositories, and ointments)
7. Toxicity
8. Specific activity
9. Master strains
10. Packaging, labeling, transportation, storage
11. Shelf life
12. Intended use

### **Immunomodulators**

1. Introductory part
2. Description
3. Identification
4. Solubility (for dry products)
5. Clarity
6. Colority
7. pH
8. Loss on drying (for dry products)
9. Vacuum (shielding gas, hermetization)
10. Chemical tests (protein; total and protein nitrogen; nucleic acids; polysaccharides, etc.)
11. Sterility
12. Pyrogens
- 13.<sup>\*</sup>Bacterial endotoxins
14. Toxicity
- 15.<sup>\*</sup>Specific safety
- 16.<sup>\*</sup> HBsAg and antibodies to HIV-1 and HIV-2 absence tests (other human blood contaminants in case of determined necessity)
17. Specific activity
18. Impurities
19. Adjuvants

20. Packaging, labeling, transportation, storage
21. Shelf life
22. Intended use

### **Allergens and allergoids**

1. Introductory part
2. Description
3. Identification
4. pH
5. Protein nitrogen
6. Sterility
7. Toxicity
8. Specific activity
9. Adjuvants
10. Solvents and reagents included with the product
11. Packaging, labeling, transportation, storage
12. Shelf life
13. Intended use

### **Probiotics**

1. Introductory part
2. Description
3. Identification
4. Dissolution (disintegration)
5. Average mass (for tablets, suppositories, and capsules)
6. <sup>\*</sup>pH
7. Loss on drying
8. <sup>\*</sup>Vacuum (shielding gas, hermetization)
9. Safety
10. Absence of foreign microorganisms and fungi, or microbiological purity
11. Specific activity
12. Master strains
13. Packaging, labeling, transportation, storage
14. Shelf life
15. Intended use

**Diagnostic products**

1. Introductory part
2. Description
3. Identification
4. Solubility (for dry products)
5. <sup>\*</sup>pH
6. Vacuum (shielding gas, hermetization)
7. Loss on drying
8. Sterility, or microbiological purity
9. Specific activity
10. Master strains
11. Adjuvants
12. Packaging, labeling, transportation, storage
13. Shelf life
14. Intended use

**Immunoenzyme and polymerase chain reaction-based test-systems**

1. Introductory part
2. Description
3. Identification
4. <sup>\*</sup>Solubility
5. pH
6. <sup>\*</sup>Vacuum (shielding gas, hermetization)
7. <sup>\*</sup>Loss on drying
8. <sup>\*</sup>Sterility, or microbiological purity
9. Specific activity
10. Packaging, labeling, transportation, storage
11. Shelf life
12. Intended use

**Bacteriological nutrient media**

1. Introductory part
2. Description
3. Solubility

4. Clarity
5. Colority
6. Solution pH (extract pH for agar-containing media)
7. Loss on drying
- 8.<\*>Total nitrogen
9. Amine nitrogen
10. Chlorides
- 11.<\*>Carbohydrates
12. Gel strength (for solid media)
13. Specific activity (medium sensitivity, growth rate and stability of the principal biological properties of microorganisms, and inhibitory and differentiative properties, the set of which and the procedures used depend on the intended use of a medium)
14. Packaging, labeling, transportation, storage
15. Shelf life
16. Intended use

#### **Nutrient media, solutions, and growth factors for cell cultivation**

1. Introductory part
2. Description
3. Solubility (for dry products)
4. Clarity
5. Colority
6. pH
7. Loss on drying (для сухих препаратов)
- 8.<\*>Chloride ion
- 9.<\*>Glucose
- 10.<\*>Amine nitrogen
- 11.<\*>Protein
- 12.<\*>Buffer capacity
- 13.<\*>Osmosity
- 14.<\*> Osmolarity
15. Sterility
- 16.<\*>Toxicity
17. Specific activity

18. <\*>Impurities
19. Packaging, labeling, transportation, storage
20. Shelf life
21. Intended use

## **XV. Human blood products**

### **Liquid pharmaceutical forms of blood products**

1. Product name in Russian
2. Content of the active component in % or specific activity units
3. Composition
4. Description
5. Clarity
6. Colority
7. pH
8. Identification, including the verification of homology with human blood proteins
9. Assay of the principal protein component
10. Fractional protein composition
11. Specific activity
12. Molecular parameters of the principal protein component
13. Hemagglutinins (anti-A and anti-B)
14. Thrombogenicity (for coagulolytic products)
15. Prekallikrein activator
16. Anticomplementary activity
17. Thermostability
18. Electrolytes (sodium, potassium, citrate, calcium, aluminum, etc.)
19. Impurities
20. Absence of particulate contamination
21. Nominal volume
22. Pyrogens
23. Bacterial endotoxins
24. Toxicity
25. Content of hemolytic substances
26. Test for the absence of antigens (antibodies) to hepatitis and human immunodeficiency viruses and other possible human blood contaminants

27. Sterility
28. Packaging, labeling, transportation, storage
29. Shelf life
30. Pharmacological group

### **Dry and frozen pharmaceutical forms of blood products**

1. Product name in Russian
2. Content of the active component in mg specific activity units
3. Composition
4. Characteristics of the included solvent, activator, or plasticizer
5. Description of the finished pharmaceutical form, and also following its dissolution (unfreezing)
6. Solubility, or time of dissolution in the included solvent (for dry products)
7. Clarity
8. Colority (hem pigments)
9. Solution pH
10. Identification, including the verification of homology with human blood proteins
11. Assay of the principal protein component
12. Fractional protein composition
13. Specific activity
14. Molecular parameters of the principal protein component
15. Hemagglutinins (anti-A and anti-B)
16. Thrombogenicity (for coagulolytic products)
17. Prekallikrein activator
18. Anticomplementary activity
19. Thermostability
20. Electrolytes (sodium, potassium, citrate, calcium, aluminum, etc.)
21. Impurities
22. Loss on drying
23. Water
24. Absence of particulate contamination
25. Nominal volume
26. Pyrogens
27. Bacterial endotoxins
28. Toxicity

29. Content of hemolytic substances
30. Test for the absence of antigens (antibodies) to hepatitis and human immunodeficiency viruses and other possible human blood contaminants
31. Sterility
32. Packaging, labeling, transportation, storage
33. Shelf life
34. Pharmacological group

### Annex 3

to the Industry Standard OST 91500.05.001-00 "Quality Standards of Medicines. Basic Provisions"

### **Arrangement and presentation of state quality standards of medicines for substances**

1. Name of the substance in Russian, international nonproprietary name (INN), and chemical name in accordance with the rules of the International Union of Pure and Applied Chemistry (IUPAC) are stated in the following order:

- Russian name;
- international nonproprietary name;
- chemical name.

2. In the middle under the name, the structural formula represented in accordance with the IUPAC's rules should be given.

3. In the empirical formula, which is given on the left under the structural formula, carbon comes first, hydrogen comes second, and the following elements including metals are stated in the alphabetical order, e.g.:  $C_{12}H_{17}ClN_4OS \cdot HCl$ .

4. The relative molecular mass should be given in accordance with the latest international atomic masses and specified to the second decimal place for relative molecular masses not exceeding 400, and to the first decimal place for relative molecular masses exceeding 400. The content of the main active ingredient is given in percent or units of activity.

5. Depending on the contents, the text of a quality standard for a substance should be divided into sections and have an introductory part, if necessary. The list of

sections and their contents should be determined in accordance with the peculiarities of physicochemical properties and the nature of a medicine.

6. Some sections can be combined; other sections can be introduced, if necessary (preparation, creation of the calibration curve, preparation of the standard solution, etc.).

7. Measurement (control) methods should be presented in the third person plural. The section "Description" is presented in form of a narration.

8. The section "Description" establishes the appearance tests for a medicine (physical state, color, and odor), possible changes when storing it in the open air or under light (indication of hygroscopicity and effects of the air and light exposure). Odor is not indicated for poisonous and potent medicines.

9. The section "Identification" specifies the characteristics of the ultraviolet (UV) and infrared (IR) absorption spectra, etc. and 2-3 reactions that are the most characteristic of this product, if necessary.

10. The section "Solubility" specifies the solubility tests with water, 95% alcohol, chloroform, and ether (if a substance is practically insoluble in ether, ether is excluded from the list of solvents). Other solvents are stated if necessary. The descriptive terms of solubility and their values are presented in accordance with the general chapter of the State Pharmacopoeia, "Solubility". In cases when the precise solubility of a medicine is determined, the ratio between the mass of the solute and the volume of the solvent is given.

11. Temperature ranges of distillation, melting, or freezing, as well as density, specific rotation, specific absorbance, refractive index, and other physical constants are presented as separate sections that specify the upper and lower limits of these quality tests.

12. The clarity and colority of solutions are specified for a certain concentration; for colored solution, the number of the colority standard and the letters of the scale are given or the corresponding characteristics of the absorption spectra of such solutions are specified.

13. When determining the acidity and alkalinity limits with the indicators, the solutions of acids or alkalis with the concentration 0.01 M to 0.1 M are used; pH is determined potentiometrically.

14. The section "Impurities (related substances)" specifies the procedure of identification and the limits for processing aids or substances formed during storage. When using chromatographic methods for this purpose, the type of

sorbent, composition of the phases, amount of the test substance to be chromatographed, amount of the reference standard (tracking substance), run time, development reagent, and all other conditions determining the chromatographic process should be specified.

15. The section "Residual solvents" should specify the colority standards that set the limits for organic impurities, or other modern methods, e.g. chromatography. The control of residual solvents is included if toxic solvents are used in the preparation procedure of a medicine and also if organic solvents are used at the final stage of the manufacturing process of a medicine.

16. The sections "Chlorides", "Sulfates", etc. specify the limits for these impurities related to the manufacturing process.

17. The sections "Loss on drying" and "Water" specify the weighting of the product, the determination procedure for Karl Fischer titration endpoint, drying conditions, and the limits for loss on drying or water content.

18. The section "Sulfate ash and heavy metals" specifies the weighting of the product and the limits for sulfate ash and heavy metals.

19. The section "Arsenic" specifies the limits for arsenic or its absence.

20. The sections "Toxicity", "Pyrogens", and "Histamine-like substances" specify test doses, methods of administration, and period of observation for the medicines tested.

21. The section "Sterility" is introduced when it is impossible to sterilize the pharmaceutical form. The section "Microbiological purity" describes the method of detection of microorganisms and their limits.

22. The section "Assay" describes the assay method for the principal substance contained in the product. This section also specifies the percentage of the principal substance or its activity in the units of activity (units/mg) with reference to the active ingredient.

23. The section "Packaging" specifies the primary package (individual package: jars, ampoules, vials, bags, etc.), number of product units in the primary package (e.g. the number of tablets in a bottle), secondary (consumer) package and the number of primary packages in it, hermetization methods, etc. References to the corresponding regulatory documents should be given for bundles and shipping package. A package should guarantee the safety of the medicine over the shelf life established.

24. The section “Labeling” is presented in accordance with the requirements of the regulatory documents to the graphic design of medicines.

25. The section “Transportation” gives a reference to the current standard. If necessary, the requirements related to loading and unloading of the products and handling of the products after transportation (e.g. the necessity to leave the products at room temperature following the transportation at negative temperatures, etc.) are specified.

26. The section “Storage” should specify the storage conditions for the products that guarantee that their quality and marketable state will remain intact and, if necessary, the requirements to protection of the products from environmental exposure (moisture, sunlight, temperature) and the peculiarities of storage for medicines that are poisonous, potent, psychotropic, narcotic, or their precursors (according to the corresponding current lists including lists A and B).

27. The section “Shelf life” specifies the period of time, within which the medicine can be used.

28. The section “Pharmacological (biological) activity” specifies the pharmacological group of the product.

29. Paragraphs 23, 24, 25, and 27 are not included into monographs.

#### Annex 4

to the Industry Standard OST 91500.05.001-00 “Quality Standards of Medicines. Basic Provisions”

#### **Arrangement, contents, and presentation of state quality standards for medicinal products**

1. The title of a standard specifies the name of the medicinal product in Russian.
2. The first word in the name of a medicinal product should be the name of the active ingredient (in the nominative case) or its trade name (in the nominative case), followed by the name of the pharmaceutical form, dosage (concentration), and volume. Example: Analgin tablets 0.5 g or Analgin solution for injection 25%.

3. Some sections can be combined, or, if necessary, other sections can be included (acid value, saponification value, iodine value, ester value, toxicity, pyrogens, histamine-like substances, sterility, etc.).
4. A standard should have an introductory part. The introductory part specifies the chemical name of the active ingredient (for monocomponent products); Russian and Latin names of plant raw materials, producing plant and its family (for tinctures and extracts).
5. The description of the composition of a medicinal product should specify the quantitative content of active ingredients and the qualitative composition of excipients as a list with references to the corresponding regulatory documents that contain quality requirements to them.
6. The section "Description" establishes organoleptic characteristics of the appearance of a finished medicine (color and odor). Attributes such as azure, egg, etc. must not be used. The principal color is specified at the end of the attribute, e.g. greenish blue (blue color with a tinge of green).
7. The section "Disintegration" specifies the time of total disintegration of a tablet or a capsule in a liquid medium (under the conditions stated in the State Pharmacopoeia).
8. The section "Identification" is given fully as described under Paragraph 9 Annex 3 to this OST.  
For complex products, the identified ingredient is given in brackets after the description of the required determination.
9. The sections "Clarity" and "Colority" establish the clarity (turbidity) and color of the medicinal product compared to a solvent or the corresponding standard.
10. The section "Acidity", "Alkalinity", or "pH" is given fully as described under Paragraph 13 Annex 3 to this OST.
11. The sections "Dry residue", "Alcohol content", "Boiling point", "Density", "Refractive index", "Angle of rotation", and "Viscosity" specify the upper and lower limits of these quality tests in the corresponding measurement units.
12. The section "Dissolution" establishes the amount of the active ingredient that should pass into a solution within a specific period of time under the given conditions.
13. The section "Assay" describes the assay method for the active ingredient contained in the medicinal product.

This section also specifies the percentage of the active ingredient or activity in units of activity or micrograms to milligrams with reference to the active ingredient (units/mg or µg/mg) in the medicinal product or its pharmaceutical forms.

The limits of the content of the active ingredient in grams per tablet with reference to the average mass of tablets are specified for tablets, in grams per suppository for suppositories, in grams per pill for pills, and in grams per ml for solutions for injections.

14. The section “Microbiological purity” is given as described under Paragraph 21 Annex 3 to this OST.

15. The sections “Packaging”, “Labeling”, “Transportation”, and “Storage” are given as described under Paragraphs 23-25 to this OST.

16. The section “Shelf life” is given as described under Paragraph 27 Annex 3 to this OST.

17. The section “Pharmacological activity” is given as described under Paragraph 28 Annex 3 to this OST.

18. Paragraphs 6, 15, and 16 are included into monographs if necessary.

## Annex 5

to the Industry Standard OST 91500.05.001-00 “Quality Standards of Medicines. Basic Provisions”

### **Arrangement, contents, and presentation of state quality standards for medicinal plant raw materials**

1. The title of a standard specifies the name of the medicinal plant raw materials in Russian and in Latin.

2. Russian and Latin names of the medicinal plant raw materials are given in plural.

The first word in the name of medicinal plant raw materials should be their denomination (in the nominative case) or trade name (in the nominative case), followed by the pharmaceutical form (mixture, cake, etc.).

3. A standard should have an introductory part. The introductory part specifies: name and field of use of the medicinal plant raw materials, producing plant and its family (in Russian and Latin).
4. The section "Appearance" briefly describes the morphological characteristics of the whole and the comminuted raw materials.
5. The section "Microscopy" describes the diagnostic characters of the raw materials, illustrated with microphotographs or drawings.
6. The section "Qualitative reactions" describes the procedures of microchemical, histochemical, etc. reactions or chromatographic tests.
7. The section "Quantitative tests" establishes the limits of percentage of active ingredients (pharmacologically active substances) or biological activity, moisture limits (loss on drying), total ash and ash insoluble in 10% hydrochloric acid solution, impurities, and fragment size.
8. The section "Assay" describes the determination procedures for the content of the active ingredients.
9. The section "Microbiological purity" is given as described under Paragraph 21 Annex 3 to this OST.
10. The sections "Packaging", "Labeling", "Transportation", and "Storage" are given as described under Paragraphs 23-26 to this OST.
11. The section "Shelf life" is given as described under Paragraph 27 Annex 3 to this OST.
12. The section "Pharmacological activity" is given as described under Paragraph 28 Annex 3 to this OST.
- 4.13. Section titles start a new paragraph and are set off in boldface font or underlined.
13. Paragraphs 10, 11, and 12 are included into monographs if necessary

\* Here and elsewhere in the text: the section is introduced if necessary