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GOST according to OECD GLP protocols

1. GOST 32296-2013 "Testing of chemicals for human health. Test No. 420: Acute Oral Toxicity - Fixed Dose Procedure" (OECD№ 420).
2. GOST 32644-2014 "Testing of chemicals for human health. Acute Oral toxicity - Acute Toxic Class Method" (OECD № 423).
3. GOST 32641-2014 "Testing of chemicals for human health. Repeated dose 28-day oral toxicity study in rodents" (OECD № 407).
4. GOST 32637-2020 "Testing of chemicals for human health. Repeated dose 90-day oral toxicity study in rodents" (OECD № 408).
5. GOST 32642-2014 "Testing of chemicals for human health. Repeated Dose Dermal Toxicity: 21/28-day Study" (OECD № 410).
6. GOST 32647-2014 "Testing of chemicals for human health. Combined Chronic Toxicity/Carcinogenicity Studies" (OECD № 453).
7. GOST 32635-2014 "Testing of chemicals for human health. In Vitro Mammalian Cell Micronucleus Test" (OECD № 487).
8. GOST 32639-2014 "Testing of chemicals for human health. Subchronic Dermal Toxicity: 90-day Study" (OECD № 411).
9. GOST 32645-2014 "Testing of chemicals for human health. Neurotoxicity Study in Rodents" (OECD № 424).
10. GOST 32375-2013 "Testing of chemicals for human health. Skin Sensitisation" (OECD № 406).
11. GOST 34556-2019 "Methods of testing the chemicals of human hazard. Tests for the evaluation of skin sensitization by the method of studying the reaction of regional lymph nodes" (OECD Test № 429).
12. GOST 34557-2019 "Methods of testing the chemicals of human hazard. Testing of acute oral toxicity by intragastric admission. Up-and-down method" (OECD № 425).
13. GOST 32380-2020 "Testing of chemicals for human health. Prenatal Developmental Toxicity Study" (OECD № 414).
14. GOST 32436-2020 "Testing of chemicals for human health. Acute Dermal Irritation/Corrosion" (OECD № 404).
15. GOST 32373-2020 "Testing of chemicals for human health. Acute Dermal Toxicity " (OECD № 402).
16. GOST 32376-2013 "Testing of chemicals for human health. Bacterial Reverse Mutation Test " (OECD № 471).
17. GOST 32519-2013 "Testing of chemicals for human health. Chronic Toxicity Studies with oral administration" (OECD № 452).

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18. GOST 32383-2013 "Testing of chemicals for human health. Chronic Toxicity Studies with inhalation type of administration" (OECD № 452).
19. GOST 32437-2013 "Testing of chemicals for human health. Chronic Toxicity Studies with skin administration" (OECD № 452).
20. GOST 32378-2013 "Testing of chemicals for human health. One-Generation Reproduction Toxicity Study" (OECD № 415).
21. GOST 34658-2020 "Methods of testing the impact of chemical products on the human body. Assessment of the irritant/corrosive eye exposure (OECD Test N 405:2017)".
22. GOST 31891-2012 "Principles of Good Laboratory Practice (GLP). Application of GLP principles to *in vitro* studies" (OECD № 14).

GOST in accordance with ICH protocols

1. GOST R 56699-2015 "Medicines for medical applications. Preclinical safety evaluation of biotechnology-derived pharmaceuticals. General recommendations" (ICH S6(R1):2011).
2. GOST R 56700-2015 "Medicines for medical applications. Safety Pharmacology studies for human pharmaceuticals" (ICH S7A:2001).
3. GOST R 56701-2015 "Medicines for medical applications. Guidance on nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals" (ICH M3(R2):2009).
4. GOST R 56702-2015 "Medicines for medical applications. Nonclinical toxicology and pharmacokinetic studies of safety" (ICH S3A:1994).
5. GOST R 57129-2016 "Medicines for medical application. Part 1. Stability testing of new drug substances and products. General" (ICH Q1A:2003).
6. GOST R 57130-2016 "Medicines for medical application. Genotoxicity testing and data interpretation" (ICH S2:2011).
7. GOST R 57146-2016 "Medicines for medical application. Study for carcinogenicity of pharmaceuticals and excipients" (ICH S1 A:1995, ICH S1B:1997, ICH S1C(R2):2008).
8. GOST R 57147-2016 "Medicine for medical application. Nonclinical evaluation for anticancer pharmaceuticals" (ICH S9:2009).
9. GOST R 58173-2018 "Medicines for medical application. Immunotoxicity investigations intended for humans pharmaceuticals" (ICH S8:2005).

GOST ISO 10993 Medical devices

1. GOST ISO 10993-1-2021 "Medical devices. Biological evaluation of medical devices. Part 1. Evaluation and testing".
2. GOST ISO 10993-3-2021 "Medical devices. Biological evaluation of medical devices. Part 3. Tests for genotoxicity, carcinogenicity and reproductive toxicity".
3. GOST ISO 10993-4-2020 "Medical devices. Biological evaluation of medical devices. Part 4. Selection of tests for interactions with blood".

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4. GOST ISO 10993-5-2011 "Medical devices. Biological evaluation of medical devices. Part 5. Test for in vitro cytotoxicity".
5. GOST ISO 10993-6-2021 "Medical devices. Biological evaluation of medical devices. Part 6. Test for local effects after implantation".
6. GOST ISO 10993-9-2015 "Medical devices. Biological evaluation of medical devices. Part 9. Framework for identification and quantification of potential degradation products".
7. GOST ISO 10993-10-2011 "Medical devices. Biological evaluation of medical devices. Part 10. Tests for irritation and delayed-type hypersensitivity".
8. GOST ISO 10993-11-2021 "Medical devices. Biological evaluation of medical devices. Part 11. Tests for systemic toxicity".
9. GOST ISO 10993-12-2015 "Medical devices. Biological evaluation of medical devices. Part 12. Sample preparation and reference materials".
10. GOST ISO 10993-16-2021 "Medical devices. Biological evaluation of medical devices. Part 16. Toxicokinetic study design for degradation products and leachables".
11. GOST ISO/TS 10993-20-2011 "Medical devices. Biological evaluation of medical devices. Part 20. Principles and methods for immunotoxicology testing of medical devices".

Standards for microbiological assessment of perfumery and cosmetic products

1. CU TR 009/2011 "On the security of perfumes and cosmetics".
2. GOST 29188.0-2014 "Perfume and cosmetic products. Acceptance rules, sampling, organoleptic test methods".
3. GOST ISO 21148-2020 "Perfume and cosmetic products. Microbiology. General instructions for microbiological examination".
4. GOST ISO 21149-2020 2013 "Perfume and cosmetic products. Microbiology. Enumeration and detection of aerobic mesophilic bacteria".
5. GOST 7983-99 "Toothpastes. General specifications" (with Amendment).
6. GOST ISO 18416-2018 "Perfume and cosmetic products. Microbiology. Detection of Candida albicans".
7. GOST ISO 21150-2018 "Perfume and cosmetic products. Microbiology. Detection of Escherichia coli".
8. GOST ISO 22718-2018 "Perfume and cosmetic products. Microbiology. Detection of Staphylococcus aureus".
9. GOST ISO 22717-2018 "Perfume and cosmetic products. Microbiology. Detection of Pseudomonas aeruginosa".
10. GOST 33918-2016 "Perfume and cosmetic products. Microbiology. Method of determination of sterility".
11. GOST 33506-2015 "Perfume and cosmetic products. Microbiology. Method of determination and assessment of toxicological safety indicators".

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Standards for Microbiological Assessment of Animal Feed

1. GOST 13586.3-2015 "Grain. Acceptance rules and sampling methods".
2. GOST 32064-2013 "Food products. Methods for detection and quantity determination of family Enterobacteriaceae".
3. GOST 32011-2013 (ISO 16654:2001) "Microbiology of food and animal feeding stuffs. Horizontal method for the detection of Escherichia coli O157".
4. GOST ISO 21527-1-2013 "Microbiology of food and animal feeding stuffs. Method for the enumeration of yeasts and moulds. Part 1: Colony count technique in products with water activity greater than 0,95".
5. GOST ISO 21871-2013 "Microbiology of food and animal feeding stuffs. Most probable number count and detection method for Bacillus cereus".
6. GOST 13496.6-2017 "Mixed feed. Method of detachment of fungi".
7. GOST 27668-88 "Flour and bran. Acceptance and sampling methods" (with Modifications No 1 and No 2).
8. GOST 13979.0-86 "Oilcakes, oilmeals and powdered mustard seed cake. Acceptance rules and methods of sampling".
9. GOST 13456-82 "Dried beat-root cake for export. Specifications".
10. GOST 25311-82 "Feeding flour of animal origin. Methods of bacteriological analysis" (with Modification No 1).
11. GOST ISO 7218-2015 "Microbiology of food and animal feed. General requirements and guidance for microbiological examinations".
12. GOST 17536-82 "Feeding flour of animal origin. Specifications" (with Modifications No 1, No 2 and No 3).
13. GOST 2116-2000 "Meal from fish, marine mammals, crustaceous and invertebrates. Specifications" (with Modification No 1).
14. GOST ISO 10272-1-2013 "Microbiology of food and animal feeding stuffs. Methods for detection and enumeration of Campylobacter spp. Part 1. Detection method".
15. GOST ISO 10272-1-2013 "Microbiology of food and animal feeding stuffs. Methods for detection and enumeration of Campylobacter spp. Part 1. Detection method".
16. GOST R 55027-2012/ISO/TS 10272-3:2010 "Microbiology of food and animal feeding stuffs. Horizontal method for detection and enumeration of Campylobacter spp. Part 3. Semi-quantitative method".
17. GOST 20083-74 "Feeding stuff yeast. Specifications" (with Modifications No 2-7).

Standards for microbiological assessment of environmental factors and objects, industrial facilities (workplaces, industrial zones)

1. GOST 31861-2012 "Water. General requirements for sampling".
2. GOST 31942-2012 "Water. Sampling for microbiological analysis".
3. GOST 31955.1-2013 (ISO 9308-1:2000) "Drinking water. Detection and enumeration of Escherichia coli and coliform bacteria. Part 1. Membrane filtration method" (with Amendment).

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4. GOST R 54316-2020 "Drinking natural mineral waters. General specifications".
5. GOST 17.4.3.01-2017 "Nature protection (SSOP). Soils. General requirements for sampling".
6. GOST 17.4.4.02-2017 "Nature protection (SSOP). Soils. Methods for sampling and preparation of soil for chemical, bacteriological and helmintoglogical analysis".
7. GOST R 52539-2006 "Air cleanliness in hospitals. General requirements".

Standards for evaluating the antimicrobial activity of drugs

1. GOST R ISO 20776-1-2010 "Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 1. Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases".
2. GOST R ISO 20776-2-2010 "Clinical laboratory testing and in vitro diagnostic test systems. Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices. Part 2. Evaluation of performance of antimicrobial susceptibility test devices".
3. GOST R ISO 16256-2015 "Clinical laboratory testing and in vitro diagnostic test systems. Reference method testing the in vitro activity of antimicrobial agents against yeast fungi involved in infectious diseases".

State Pharmacopoeia of the Russian Federation XIV (OFS)

1. OFS.1.1.0006.15 "Pharmaceutical substances".
2. OFS.1.1.0009.18 "Shelf life of drugs".
3. OFS.1.1.0012.15 "Validation of analytical methods".
4. OFS.1.1.0015.15 "Sieve Analysis".
5. OFS.1.1.0020.18 "Stability of biological drugs".
6. OFS.1.1.0023.18 "Related impurities in pharmaceutical substances and drugs".
7. OFS.1.2.1.0003.15 "Osmolarity".
8. OFS.1.2.1.0004.15 "Ionometry".
9. OFS.1.2.1.0005.15 "Solubility".
10. OFS.1.2.1.0006.15 "Degree of color of liquids".
11. OFS.1.2.1.0007.15 "Transparency and degree of turbidity of liquids".
12. OFS.1.2.1.0009.15 "Optical microscopy".
13. OFS.1.2.1.0010.15 "Loss on drying".
14. OFS.1.2.1.0014.15 "Density".
15. OFS.1.2.1.0021.15 "Electrophoresis".
16. OFS.1.2.1.0023.15 "Polyacrylamide Gel Electrophoresis".
17. OFS.1.2.1.1.0003.15 "Ultraviolet-visible Spectrophotometry".
18. OFS.1.2.1.1.0006.15 "Fluorimetry".
19. OFS.1.2.1.1.0012.18 "Photocolorimetry".

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20.OFS.1.2.1.2.0001.15 "Chromatography".
21.OFS.1.2.1.2.0002.15 "Paper Chromatography".
22.OFS.1.2.1.2.0003.15 "Thin layer chromatography".
23.OFS.1.2.1.2.0005.15 "High performance liquid chromatography".
24.OFS.1.2.1.2.0007.18 "Size exclusion chromatography".
25.OFS.1.2.1.2.0008.18 "Ion exchange chromatography".
26.OFS.1.2.2.2.0012.15 "Heavy metals".
27.OFS.1.2.2.2.0013.15 "Total ash".
28.OFS.1.2.2.2.0014.15 "Sulfated ash".
29.OFS.1.2.3.0004.15 "Acid number".
30.OFS.1.2.3.0005.15 "Iodine number".
31.OFS.1.2.3.0006.15 "Hydroxyl number".
32.OFS.1.2.3.0007.15 "Peroxide number".
33.OFS.1.2.3.0008.15 "Saponification number".
34.OFS.1.2.3.0011.15 "The Kjeldahl method for organic nitrogen".
35.OFS.1.2.3.0012.15 "Protein determination".
36.OFS.1.2.3.0019.15 "Determination of sugars by spectrophotometric method".
37.OFS.1.2.3.0021.15 "Determination of the adsorption activity of enterosorbents".
38.OFS.1.2.4.0006.15 "Bacterial endotoxins".
39.OFS.1.2.4.0007.15 "Histamine test".
40.OFS.1.2.4.0013.15 "Determination of the activity of enzyme drugs".
41.OFS.1.4.1.0001.15 "Dosage Forms".
42.OFS.1.4.1.0002.15 "Aerosols and sprays".
43.OFS.1.4.1.0003.15 "Eye Dosage Forms".
44.OFS.1.4.1.0004.18 "Granules".
45.OFS.1.4.1.0005.18 "Capsules".
46.OFS.1.4.1.0007.15 "Parenteral dosage forms".
47.OFS.1.4.1.0008.18 "Ointment".
48.OFS.1.4.1.0010.15 "Powders".
49.OFS.1.4.1.0011.18 "Solutions".
50.OFS.1.4.1.0012.15 "Syrups".
51.OFS.1.4.1.0013.15 "Suppositories".
52.OFS.1.4.1.0014.15 "Suspensions".
53.OFS.1.4.1.0015.15 "Tablets".
54.OFS.1.4.1.0017.15 "Emulsions".
55.OFS.1.4.1.0018.15 "Infusions and decoctions".
56.OFS.1.4.1.0019.15 "Tinctures".
57.OFS.1.4.1.0020.15 "Aids".
58.OFS.1.4.1.0021.15 "Extracts".
59.OFS.1.4.1.0027.18 "Drops".
60.OFS.1.4.1.0029.18 "Concentrates".
61.OFS.1.4.1.0031.18 "Lyophilizates".
62.OFS.1.4.2.0002.18 "Recoverable volume".

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63.OFS.1.4.2.0003.15 "Retrievable volume of dosage forms for parenteral use".
64.OFS.1.4.2.0004.15 "Friability test".
65.OFS.1.4.2.0005.18 "Visible particulate matter in parenteral and ophthalmic formulations".
66.OFS.1.4.2.0007.15 "Mass (volume) of the contents of the package".
67.OFS.1.4.2.0008.18 "Uniformity of dosing".
68.OFS.1.4.2.0009.15 "Mass uniformity of dosage forms".
69.OFS.1.4.2.0011.15 "Crush strength of tablets".
70.OFS.1.4.2.0012.15 "Disintegration of suppositories and vaginal tablets".
71.OFS.1.4.2.0013.15 "Disintegration of tablets and capsules".
72.OFS.1.4.2.0014.15 "Dissolution for solid dosage forms".
73.OFS.1.4.2.0016.15 "The degree of flowability of powders".
74.OFS.1.5.3.0005.15 "Ash insoluble in hydrochloric acid".
75.OFS.1.7.1.0002.15 "Bacteriophages".
76.OFS.1.7.1.0010.18 "Biological drugs".
77.OFS.1.7.2.0018.15 "Determination of nucleic acids by the method of Spirin in biological drugs".
78.OFS.1.7.2.0023.15 "Determination of protein by colorimetric method (Lowry method) in biological drugs".
79.OFS.1.7.2.0028.18 "Quantitative determination of phenol in biological drugs".
80.OFS.1.7.2.0033.15 "Enzyme immunoassay method".
81.OFS.1.7.2.0037.18 "Determination of mannitol (mannitol) in biological drugs".
82.OFS.1.8.2.0003.18 "Determination of blood coagulation factor activity".
83.OFS.1.8.2.0010.18 "Quantitative determination of protein by colorimetric method with biuret reagent in human and animal blood preparations".
84.OFS 1.2.4.0004.15 "Abnormal toxicity".
85.OFS.2.2.0020.15 "Purified water".
86.OFS.1.2.4.0002.18 "Microbiological purity".
87.OFS.1.2.4.0010.18 "Determination of antimicrobial activity of antibiotics by agar diffusion method".
88.OFS.1.2.4.0003.15 "Sterility".
89.OFS.1.2.4.0005.15 "Pyrogenicity".
90.OFS.1.2.4.0008.15 "Depressant test".
91.OFS.1.2.4.0001.15 "Biological testing of insulin".

Other documents

1. Guidelines for the expertise of medicines. Vol I. – M.: Grif, 2013. – 328 p.
2. Guidelines for the expertise of medicines. Vol II. – M.: Grif, 2013. – 280 p.
3. Guidelines for the expertise of medicines. Vol. III. M.: POLYGRAPH-PLUS, 2014. Chapter 11 "Guidelines for the study of the comparative dissolution kinetics of solid dosage forms".

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4. Guidelines for the expertise of medicines. Vol IV. Edited by Mironov A.N.– M.: POLYGRAPH-PLUS, 2014. – 344 p.
5. OST 64-02-003-2002 Standard Industry "Products of the medical industry." Technological order of production.
6. GOST R 57129-2016 Medicines for medical application. Part 1. Stability testing of new drug substances and products. General
7. GOST 31460-2012 Cosmetic creams. General specifications
8. ICH Topic Q8 (R2). Pharmaceutical Development (EMEA/CHMP/167068/2004);
9. Guidance for Industry: Bioanalytical method for validation – Rockville, MD, U.S., 2018. – 41p.
10. Guideline on bioanalytical method validation. EMEA/CHMP/EWP192217/2009 – London, 2011. – 23p.
11. 1.3AQ1a Guideline Title Development Pharmaceutics and Process Validation.
12. ICH, Q2A, Harmonized tripartite guideline, text on validation of analytical procedures, IFPMA – Geneva, March 1994. – P. 1–5.
13. ICH, Q2B, Harmonized tripartite guideline, validation of analytical procedure: methodology, IFPMA, in: Proceedings of the International Conference on Harmonization – Geneva, 1996. – P. 1–8.
14. ICH Topic Q9. Quality Risk Management;
15. ICH Topic Q10. Pharmaceutical Quality System.

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