CERTIFICATE OF THE FEDERAL AGENCY FOR TECHNICAL REGULATION AND METROLOGY
№ РОСС RU.M335.04BE00

CERTIFICATE

This is to certify that

"St. Petersburg Institute of Pharmacy" Closed Joint Stock Company

3, Zavodskaya str, Bldg. 245, Kuzmolovsky settlement, Vsevolozhsky District, 188663, Leningrad region, Russia

has been audited within the frameworks of the quality management system audit of Research-and-manufacturing company "HOME OF PHARMACY" Joint Stock Company

in respect of the processes performed by it: pharmacokinetics, toxicokinetics, pharmacodynamics, pharmaceutical development of new medicines, in vitro and in vivo evaluation of activity and safety of test objects which are contained in drugs, pesticides, cosmetic products, veterinary preparations, food and feed additives and chemicals for industrial use, scientific research, physical-chemical methods for analyzing of substances and drugs, chromatographic methods

The management system Research-and-manufacturing company "HOME OF PHARMACY" Joint Stock Company has been recognized conforming to the requirements of

GOST 33044-2014

Principles of good laboratory practice (GLP)

No: 19.0291.026-1
of 18th March, 2019

Management system certified since 2016

This certificate is valid until **23rd March, 2022**

Director General of Certification Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (http://www.rusregister.ru/doc/004.00-105.pdf). This Certificate is the property of Certification Association "Russian Register". This certificate becomes invalid if certificate No 19.0291.026 is suspended or canceled.

Certification Association "Russian Register": 101 Rimskogo-Korsakova Ave., 190121, Saint Petersburg, Russia

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

Annex 1 to the Certificate
№ 19.0291.026-1
of 18th March, 2019

Methods of preclinical trials of "St. Petersburg Institute of Pharmacy" Closed Joint Stock Company:

GOST in accordance with the protocols of ICH

1. GOST R 56699-2015 Medicines for medical applications. Preclinical safety evaluation of biotechnology-derived pharmaceuticals. General recommendations (ICH 56(R1):2011).
2. 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).
3. GOST R 56702-2015 Medicines for medical applications. Nonclinical toxicology and pharmacokinetic studies of safety (ICH S3A:1994, ICH S3B:1994).
4. GOST R 57688-2017 Medicines for medical applications. Stability testing of biotechnological/biological medications (ICH Q5C:1995).

GOST in accordance with the protocols of OECD GLP

1. GOST 31891-2012 Principles of Good Laboratory Practice (GLP). Application of GLP principles to in vitro studies (OECD № 14).
2. GOST 32644-2014 OECD guidelines for the testing of chemicals Acute Oral Toxicity - Acute Toxic Class Method (OECD № 423).
3. GOST 32641-2014 OECD guidelines for the testing of chemicals. Repeated dose 28-day oral toxicity study in rodents (OECD № 407).
4. GOST 32635-2014 OECD guidelines for the testing of chemicals. In Vitro Mammalian Cell Micronucleus Test (OECD № 487).
5. GOST 32379-2013 Testing of chemicals of human hazard. Reproduction/developmental toxicity screening test (OECD № 421).
6. GOST 32375-2013 Testing of chemicals of human hazard. Skin sensitisation (OECD № 406).

Director General of Certification
Association "Russian Register" A. Vladimirtsev

Annex 2 to the Certificate
№ 19.0291.026-1
of 18th March, 2019

Methods of preclinical trials of "St. Petersburg Institute of Pharmacy" Closed Joint Stock Company:

State Pharmacopoeia of the Russian Federation XIV (OFS)

1. OFS.1.2.1.0003.15 Osmolarity.
2. OFS.1.2.1.0004.15 Ionometry.
3. OFS.1.2.1.0005.15 Solubility.
4. OFS.1.2.1.0010.15 Loss on drying.
5. OFS.1.2.1.0021.15 Electrophoresis.
6. OFS.1.2.1.0023.15 Polyacrylamide Gel Electrophoresis
7. OFS.1.2.1.1.0003.15 Ultraviolet-visible Spectrophotometry.
8. OFS.1.2.1.1.0006.15 Fluorimetry.
9. OFS.1.2.1.1.0012.15 Photocolorimetry.
10. OFS.1.2.1.2.0001.15 Chromatography.
11. OFS.1.2.1.2.0002.15 Paper Chromatography.
12. OFS.1.2.1.2.0003.15 Thin layer chromatography.
13. OFS.1.2.1.2.0005.15 High performance liquid chromatography.
14. OFS.1.2.1.2.0007.18 Size exclusion chromatography.
15. OFS.1.2.1.2.0008.18 Ion exchange chromatography.
16. OFS.1.2.2.2.0012.15 Heavy metals.
17. OFS.1.2.2.2.0013.15 Total ash.
18. OFS.1.2.2.2.0014.15 Sulfated ash.
19. OFS.1.2.3.0011.15 The Kjeldahl method for organic nitrogen
20. OFS.1.2.3.0012.15 Protein determination.
21. OFS.1.2.4.0006.15 Bacterial endotoxins.
22. OFS.1.2.4.0007.15 Histamine test.
23. OFS.1.2.4.0013.15 Determination of the activity of enzyme drugs.
24. OFS.1.4.1.0001.15 Dosage Forms
25. OFS.1.4.1.0002.15 Aerosols and sprays.
26. OFS.1.4.1.0003.15 Eye Dosage Forms
27. OFS.1.4.1.0004.15 Granules
28. OFS.1.4.1.0005.15 Capsules
29. OFS.1.4.1.0006.15 Dosage forms for inhalation
30. OFS.1.4.1.0007.15 Parenteral dosage forms.
31. OFS.1.4.1.0008.15 Ointment
32. OFS.1.4.1.0011.15 Solutions
33. OFS.1.4.1.0012.15 Syrups
34. OFS.1.4.1.0013.15 Suppositories
35. OFS.1.4.1.0014.15 Suspensions
36. OFS.1.4.1.0015.15 Tablets
37. OFS.1.4.1.0017.15 Emulsions
38. OFS.1.4.1.0021.15 Extracts

Director General of Certification
Association "Russian Register" A. Vladimirtsev

Annex 3 to the Certificate
№ 19.0291.026-1
of 18th March, 2019

Methods of preclinical trials of "St. Petersburg Institute of Pharmacy" Closed Joint Stock Company:

39. OFS.1.4.2.0001.15 Aerodynamic distribution of fine particles
40. OFS.1.4.2.0004.15 Friability test
41. OFS.1.4.2.0008.18 Uniformity of dosing.
42. OFS.1.4.2.0009.15 Mass uniformity of dosage forms.
43. OFS.1.4.2.0012.15 Disintegration of suppositories and vaginal tablets
44. OFS.1.4.2.0013.15 Disintegration of tablets and capsules
45. OFS.1.4.2.0014.15 Dissolution for solid dosage forms.
46. OFS.1.4.2.0015.15 Dissolution for suppositories on lipophilic basis
47. OFS.1.7.2.0033.15 Enzyme immunoassay method.
48. OFS.1.8.2.0003.15 Determination of blood coagulation factor activity.
49. OFS.1.1.0010.15 Drug storage
50. OFS.1.1.0012.15 Validation of analytical methods
51. OFS.1.1.0009.15 Shelf life of drugs.

Other documents

1. 3AQ1a Guideline Title Development Pharmaceutics and Process Validation.
2. 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".
3. Guidelines for the expertise of medicines. Vol. I. M.: POLYGRAPH-PLUS, 2013. Chapter 7 "The study of the bioequivalence of generic drugs".
4. OST 64-02-003-2002 Standard Industry "Products of the medical industry. Technological order of production.
5. Pharmaceutical development: concept and practical recommendations. Scientific and practical guide for the pharmaceutical industry / Ed. S.N. Bykovskogo - M. Publishing House Perot, 2015.

Director General of Certification
Association "Russian Register" A. Vladimirtsev