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

CERTIFICATE

This is to certify that the Quality Management System of

Research-and-manufacturing company "HOME OF PHARMACY" Joint Stock Company

Legal address: 3, Zavodskaya Str., Bldg. 245, room 4.34, Kuz'molovskiy settlement, Vsevolozhskiy district, 188663, Leningrad region, Russia
Actual address: 3, Zavodskaya Str., Bldg. 245, Kuz'molovskiy town, Vsevolozhskiy district, 188663, Leningrad region, Russia

has been assessed and found to be in accordance with the requirements of

GOST 33044-2014

Principles of good laboratory practice (GLP)

in respect of pharmaceutical development of new medical products, scientific research, preclinical studies of general and specific toxicity, pharmaceutical safety, pharmacokinetics, pharmacodynamics and microbiological studies

No: 19.0291.026
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".

RUSSIAN REGISTER РУССКИЙ РЕГИСТР

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

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

Certification scope of management system of research-and-manufacturing company "HOME OF PHARMACY" Joint Stock Company includes:

1. **"St. Petersburg Institute of Pharmacy" Closed Joint Stock Company**
   3, Zavodskaya Str, Bldg. 245, Kuzmolovsky settlement, Vsevolozhsky District, 188663, Leningrad region, Russia

   Kinds of activity: 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.

2. **"Institute of Pre-Clinical Research" Ltd.**
   Legal address: 3, Zavodskaya Str., Bldg. 245, room 3.06, Kuz'molovskiy settlement, Vsevolozhskiy district, 188663, Leningrad region, Russia
   Actual address: 3, Zavodskaya Str., Bldg. 245, Kuzmolovskiy settlement, Vsevolozhskiy district, 188663, Leningrad region, Russia

   Kinds of activity: pharmacodynamics, safety pharmacology, general and specific toxicity studies of pharmaceuticals, microbiological studies concerning the effects of chemical products on human body, biological evaluation of pharmaceuticals, microbiological evaluation of perfumery and cosmetic products, animal feed, pesticides, environmental objects and factors , industrial facilities, medicinal products, antimicrobial activity evaluation of human and animal pharmaceuticals.

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

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

Methods of preclinical trials of Research-and-manufacturing company " HOME OF PHARMACY" Joint Stock Company:

GOST OECD GLP

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 32637-2014 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 32379-2013 Testing of chemicals for human health. Reproduction/Developmental Toxicity Screening Test (OECD № 421).
11. GOST 32375-2013 Testing of chemicals for human health. Skin Sensitisation (OECD № 406).
12. GOST 32380-2013 Testing of chemicals for human health. Prenatal Developmental Toxicity Study (OECD № 414).
13. GOST 32436-2013 Testing of chemicals for human health. Acute Dermal Irritation/Corrosion (OECD № 404).
14. GOST 32373-2013 Testing of chemicals for human health. Acute Dermal Toxicity (OECD № 402).

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

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

Methods of preclinical trials of Research-and-manufacturing company " HOME OF PHARMACY" Joint Stock Company:

15. GOST 32376-2013 Testing of chemicals for human health. Bacterial Reverse Mutation Test (OECD № 471).
16. GOST 32519-2013 Testing of chemicals for human health. Chronic Toxicity Studies with oral administration (OECD № 452).
17. GOST 32383-2013 Testing of chemicals for human health. Chronic Toxicity Studies with inhalation type of administration (OECD № 452).
18. GOST 32437-2013 Testing of chemicals for human health. Chronic Toxicity Studies with skin administration (OECD № 452).
19. GOST 32378-2013 Testing of chemicals for human health. One-Generation Reproduction Toxicity Study (OECD № 415).
20. GOST 34311-2017 Guidance on the GLP requirements for peer review of histopathology (OECD № 16).

GOST ICH

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).
10. GOST R 57688-2017 Medicines for medical application. Quality of biotechnological products: stability testing of biotechnological/biological products (ICH Q5C:1995).

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