

## COUNCIL OF EUROPE

### European Directorate for the Quality of Medicines & HealthCare

#### OMCL NETWORK QUALITY MANAGEMENT SYSTEM

#### ATTESTATION

The EDQM, European Directorate for the Quality of Medicines & HealthCare, hereby declares that

#### **FSBI "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of the Russian Federation**

**Address:** 123182 Schukinskaya street 6, building 1, Moscow, Russian Federation

**Sections audited:** Control and Coordination Laboratory, Laboratory of Antibiotics, Laboratory of Chemico-Pharmaceutical Preparations No. 2, Laboratory of Biotechnological Products (including the Spectral Methods Sector), Laboratory of Vitamins, Hormones and Synthetic Analogues, Laboratory of Herbal and Homeopathic Products, Microbiology Laboratory

has been audited in accordance with the EDQM instruction *ISO7/02 (V.10)* on the OMCL Network Mutual Joint Audit Scheme.

The above-mentioned OMCL is entitled to declare that it has satisfactorily implemented a Quality Management System in accordance with *ISO/IEC 17025:2005*, with the relevant texts of the *European Pharmacopoeia*, with the *Quality Management Guidelines* and the *Terms of Reference* of the General European OMCL Network.

Detailed information can be found in the Audit Report, which is consigned in document **PA/PH/OMCL-QA (19) 01 DEF** and the Follow-up Report **PA/PH/OMCL-QA (20) 04 DEF** corresponding to the **MJA 10/18**, as well as in the enclosed Scope of Assessment. The original documents are archived at the Department of Biological Standardisation, OMCL Network & HealthCare (DBO) of the EDQM and the Director of the OMCL has received a certified copy.

Attestation number: **EDQM/MJA-151**

Strasbourg, 20 January 2020

Valid until: **July 2023**

Laurent Mallet, Ph.D.  
Head of DBO, EDQM

