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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

State Institute for Drug Control

Srobarova 48, 100 41 Prague, Czech Republic

Sections audited: Laboratory Control Section (Analytical Chemistry Department, Biological Methods Department)

has been audited in accordance with the EDQM instruction IS07/02 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, 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 documents *PA/PH/OMCL-QA* (21) 20 DEF, *PA/PH/OMCL-QA* (22) 19 DEF and the Follow-up Report *PA/PH/OMCL-QA* (22) 26 DEF corresponding to the MJA 13/21, 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-175

Strasbourg, 7 October 2022

Valid until: 30 November 2025

Dr Michael Wierer

Head of Medicines Division, DBO, EDQM