

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
Šrobárova 48, 100 41 Prague 10, Czech Republic
Section audited: Laboratory Control Section

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 17025:2017*, 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 (20) 23 DEF** and the Follow-up Report **PA/PH/OMCL-QA (20) 28 DEF** corresponding to the **MJA 11/20**, which extends the validity of attestation *EDQM/MJA-120* for one year. 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-120-E**

Strasbourg, 1 December 2020

Valid until: **9 December 2021**



Dr Michael Wierer

Head of Medicines Division, DBO, EDQM