

## 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

**Kvetna 11, 825 08 Bratislava, Slovak Republic**

#### **Units audited: Physical-Chemical Methods Department and Biological Methods Department of the 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) 29 DEF** and the Follow-up Report **PA/PH/OMCL-QA (21) 07 DEF** corresponding to the **MJA 13/20**, which extends the validity of attestation *EDQM/MJA-145* 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-145-E**

Strasbourg, 31 March 2021

**Valid until: 12 December 2023**



Dr Michael Wierer

Head of Medicines Division, DBO, EDQM