

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

Address: Kvetna 11, 825 08 Bratislava, Slovak Republic

Section audited: Laboratory Control Section: Physical-Chemical Methods Department, Biological Methods Department

has been audited in accordance with the EDQM instruction *ISO7/02* 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 document **PA/PH/OMCL-QA (18) 19 DEF** and the Follow-up Report **PA/PH/OMCL-QA (19) 06 DEF** corresponding to the **MJA 08/18**, 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-145**

Strasbourg, 12 June 2019

Valid until: **December 2022**


Dr. Karl-Heinz Buchheit
Head of DBO, EDQM