

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

Name: National Medicines Institute

Address: 00-725 Chelmska 30/34, Warsaw, Poland

Sections audited: Synthetic Medicinal Products (LS), Antibiotics and Microbiology (MA), Biochemistry and Biopharmaceuticals (BB), Counterfeit Medicinal Products and Drugs (LF), Natural Medicinal Products and Dietary Supplements (LN), Pharmacology (FA), Medical Devices (WM), Spectrometric Methods Laboratory (PM)

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 (17) 16 DEF** and the Follow-up Report **PA/PH/OMCL-QA (18) 01 DEF** corresponding to the **MJA 07/17**, 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-126**

Strasbourg, 20 December 2017

Valid until: **June 2021**



Dr. Karl-Heinz Buchheit
Head of DBO, EDQM