

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

National Medicines Institute

Chelmska 30-34, 00-725 Warsaw, Poland

Sections audited: Synthetic Medicines Department (LS), Antibiotics and Microbiology Department (MA, Biochemistry and Biopharmaceuticals Department (BB), Falsified Medicines and Medical Devices Department (LF), Natural Medicines and Food Supplements Department (LN), Pharmacology Department (FA), Spectrometric Methods Department (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 (21) 18 DEF** and the Follow-up Report **PA/PH/OMCL-QA (22) 16 DEF** corresponding to the **MJA 11/21**, 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-169**

Strasbourg, 21 June 2022

Valid until: **1 November 2025**



Dr Michael Wierer

Head of Medicines Division, DBO, EDQM