

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

Austrian Federal Office for Safety in Health Care OMCL (Chemicals & Pharmaceuticals)

Address: Spargelfeldstrasse 191, 1220 Vienna, Austria

Sections audited: **Department Analysis of Chemical-pharmaceutical Medicinal Products (CPAA)**

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) 10 DEF** and the Follow-up Report **PA/PH/OMCL-QA (21) 22 DEF** corresponding to the **MJA 05/21**, 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-164**

Strasbourg, 3 December 2021

Valid until: **1 June 2025**



Dr. Michael Wierer

Head of Medicines Division, DBO, EDQM