

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

Agentur für Gesundheit und Ernährungssicherheit (AGES, Agency for Health and Food Safety)
Geschäftsfeld Medizinmarktaufsicht (MEA, Austrian Medicines and Medical Devices Agency)

Address: Possingergasse 38, 1160 Vienna (**BAMA**), Spargelfeldstr. 191, 1220 Vienna (**CPAA**), Traisengasse 5, 1200 Vienna (Head of OMCL, QM)

Sections audited: Department Analysis of Biological Medicinal Products (BAMA, OMCL-AT_AGES-B),
Department Analysis of Chemical-pharmaceutical Medicinal Products (CPAA, OMCL-AT_AGES-C)

has been audited in accordance with the EDQM instruction *IS7/02* 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*.

Detailed information can be found in the Audit Report, which is consigned in document **PA/PH/OMCL-QA (17) 22 DEF** and the Follow-up Report **PA/PH/OMCL-QA (17) 26 DEF** corresponding to the **MJA 02/17**, 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: **EDQMMJA-125**

Strasbourg, 24 November 2017

Valid until: **May 2021**



Dr. Karl-Heinz Buchheit
Head of DBO, EDQM