European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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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

Finnish Medicines Agency, Fimea, Laboratory

Address: Mannerheimintie 166, 00034 Helsinki, Finland

Section audited: Pharmaceutical, Chemical, Biological, Microbiological

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 (20) 06 DEF*** and the Follow-up Report ***PA/PH/OMCL-QA (20) 20 DEF*** corresponding to the **MJA 01/20,** 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-160***

Strasbourg, 2 October 2020

Valid until: ***3 February 2024***

Laurent Mallet, Ph.D.
Head of DBO, EDQM

SCOPE OF ASSESSMENT of MJA 01/20

SCOPE OF ASSESSMENT		
Products/materials tested	**Type of test**	**Test methods** (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Chemicals Active Pharmaceutical Ingredients (API) x Pharmaceutical finished dosage forms x Pharmaceutical excipients	Assay, identification and purity tests by means of high performance liquid chromatography (HPLC, detection UV/VIS) Determination of water by means of Karl-Fischer semi-micro-method Determination of water by means of Karl-Fischer micro-method Assay, identification and purity tests by means of UV/VIS-absorption Potentiometric determination of pH-values Clarity and degree of opalescence Degree of coloration of liquids Particulate contamination: sub-visible particles	In-house method based on test of the European Pharmacopeia[1)] 2.2.29 2.2.46 2.5.12 2.5.32 2.2.25 2.2.3 2.2.1 2.2.2 2.2.19
	Pharmaceutical-technological Dissolution test for solid dosage forms	 2.9.3 In-house method based on test of the European Pharmacopeia[1]
Biologicals Biological and biotech human and veterinary products	Identification and purity tests by electrophoresis - SDS-PAGE Potency/antigen quantification by means of ELISA Potency assay - cell culture/ cell based assay	2.2.31 2.7.1

SCOPE OF ASSESSMENT		
Products/materials tested	**Type of test**	**Test methods** (where applicable, reference is made to the corresponding Ph. Eur. General Method)
Chemicals x ***Biologicals*** ***x***	**Microbiological tests**: Sterility Microbiological examination of non-sterile products (total viable aerobic count) Microbiological examination of non-sterile products (test for specified micro-organisms) Bacterial endotoxins	 2.6.1 2.6.12 2.6.13 2.6.14 -Gel-clot -Kinetic chromogenic

Remarks:

The following test was removed from the scope due to missing raw data:

- Identification and purity tests by electrophoresis: - IEF