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

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

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

Finnish Medicines Agency

Mannerheiminitie 166, 00034 Helsinki, Finland

Section audited: Pharmaceutical, Chemical, Biological, Microbiological Laboratory

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 Final Audit Report, which is consigned in document ***PA/PH/OMCL-QA (15) 17 DEF*** and the Follow-up Report ***PA/PH/OMCL-QA (16) 17 DEF*** corresponding to the **MJA 10/15,** and 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-103***

Strasbourg, 28 June 2016

Valid until: ***December 2019***

Dr. Karl-Heinz Buchheit
Head of DBO, EDQM

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

SCOPE OF ASSESSMENT of MJA 10/15

SCOPE OF ASSESSMENT			
Products/materials to be tested	**Type of test**	**Test methods** (where applicable, reference made to the corresponding Ph. Eur. General Method)	**Frequency of testing in the preceding year**[2)]
Chemicals		In-house method based on test of the European Pharmacopeia [1)]	
Active Pharmaceutical Ingredients (API) x	Assay, identification and purity tests by means of high performance liquid chromatography (HPLC, detection UV/VIS, fluorescence, refractive index -RI)	2.2.29	E
Pharmaceutical finished dosage forms x		2.2.46	C
Pharmaceutical excipients x			
	Assay by means of volumetric titrations	2.2.20	C
	Determination of water by means of Karl-Fischer semi-micro-method	2.5.12	C
	Determination of water by means of Karl-Fischer micro-method	2.5.32	C
	Assay, identification and purity tests by means of UV/VIS-absorption spectrophotometry	2.2.25	D
	Identification and control of residual solvents	In-house method based on test of the EP; 2.4.24., 5.4.	A

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

SCOPE OF ASSESSMENT of MJA 10/15

SCOPE OF ASSESSMENT			
Products/materials to be tested	**Type of test**	**Test methods** (where applicable, reference made to the corresponding Ph. Eur. General Method)	**Frequency of testing in the preceding year**[2)]
	Potentiometric determination of pH-values	2.2.3	E
	Clarity and degree of opalescence	2.2.1	C
	Degree of coloration of liquids	2.2.2	C
	Uniformity of dosage units	2.9.40	C
	Particulate contamination: sub-visible particles	2.2.19	D
	Pharmaceutical-technological:		
	Uniformity of mass of single-dose preparations	2.9.5.	D
	Disintegration	2.9.1.	D
	Dissolution test for solid dosage forms	2.9.3	C
Biologicals Biological and biotech human and veterinary products		In-house method based on test of the European Pharmacopeia [1)]	
	Identification and purity tests by electrophoresis - SDS-PAGE - IEF	2.2.31	B

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

SCOPE OF ASSESSMENT of MJA 10/15

SCOPE OF ASSESSMENT			
Products/materials to be tested	**Type of test**	**Test methods** (where applicable, reference made to the corresponding Ph. Eur. General Method)	**Frequency of testing in the preceding year**[2)]
	Potency/antigen quantification by means of ELISA	2.7.1	B
Chemicals x	**Microbiological tests :**		
Biologicals x	Sterility	2.6.1	E
	Microbiological examination of non-sterile products (total viable aerobic count)	2.6.12	E
	Microbiological examination of non-sterile products (test for specified micro-organisms)	2.6.13	E
	Bacterial endotoxins	2.6.14	
		- Gel-clot	D
		- Kinetic chromogenic	C
Animal housing YES ☐/ NO X			

Remark: The audit was conducted jointly with the Finnish Accreditation Service (FINAS). The scope of the accreditation and attestation is different. The techniques "clarity and degree of opalescence, degree of coloration of liquids, uniformity of dosage units and ELISA, IEF and SDS-PAGE" in the EDQM scope were not part of the FINAS scope.