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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

Scientific Institute of Public Health (since 1/4/18 "Sciensano")

Juliette Wytsmanstraat 14, B-1050 Brussels (Belgium)

Section audited: Section of Medicines Control

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 (17) 27 DEF*** and the Follow-up Report ***PA/PH/OMCL-QA (18) 20 DEF*** corresponding to the **MJA 15/17,** 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: ***EDQM/MJA-138***

Strasbourg, 17 October 2018

Valid until: ***April 2022***

Dr. Karl-Heinz Buchheit
Head of DBO, EDQM

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SCOPE OF ASSESSMENT of MJA 15/17

Field of activity: Market surveillance testing analysis of cosmetics. Analysis for the Belgian Food Agency and for the Belgian Medicines and Health Products Agency in the field of active pharmaceutical ingredients, pharmaceutical finished dosage forms, pharmaceuticals excipients, herbals (presence of illegal substances)

Name of the OMCL: Scientific Institute of Public Health – Section of Medicines Control; since 1/4/2018 "Sciensano"

OMCL code: BE_SCIENSANO-C

Address: Juliette Wytsmanstraat 14, B-1050 Brussels (Belgium)

Head: Eric Deconinck
QA Manager: Sophie Carbonelle
Telephone: + 32 2 642 52 28
Email: Sophie.Carbonnelle@sciensano.be

History of assessments:

- MJA 15/17 Date: 21 - 23 November 2017
- MJA 04/14 Date: 8 - 10 April 2014
- MJA 01/10 Date: 26 - 28 January 2010
- MJA 02/01 Date: 26 - 27 March 2001
- MJV Date: 28 - 30 January 1998

SCOPE OF ASSESSMENT		
Products/materials to be tested	**Type of test**	**Test methods**
Chemicals Active Pharmaceutical Ingredients (API) X Pharmaceutical finished dosage forms X	Physico-chemical (Ph.Eur.), registration, in-house	Melting point (Ph. Eur. 2.2.14.) * pH (Ph. Eur. 2.2.3.) UV spectrophotometry (Ph. Eur. 2. 2.25.) IR spectrometry (Ph. Eur. 2.2.24.) optical rotation (Ph. Eur. 2.2.7.)

SCOPE OF ASSESSMENT		
Products/materials to be tested	**Type of test**	**Test methods**
Pharmaceutical excipients x Herbals (presence of illegal substances) x		relative density (Ph. Eur. 2.2.5.) HPLC/UHPLC (Ph. Eur. 2.2.29.) GC (Ph. Eur. 2.2.28.) GC-MS (Ph. Eur. 2.2.28, 2.2.43.) ** titrimetrie, loss on drying (Ph. Eur. 2.2.32.) potentiometric titration (Ph. Eur. 2.2.20.) Micro determination of water - coulometry (Ph. Eur. 2.5.32.) Semi-micro determination of water (KF) (Ph. Eur. 2.5.12.) LC-MS (Ph. Eur. 2.2.43.) TLC (Ph. Eur. 2.2.27.)
	Pharmaceutical-technological	Dissolution (Ph. Eur. 2.9.3.) Friability (Ph. Eur. 2.9.7.) Disintegration (Ph. Eur. 2.9.1.) Uniformity of mass of single dose preparations (Ph. Eur. 2.9.5.) Uniformity of content of single dose preparations (Ph. Eur. 2.9.6.)

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SCOPE OF ASSESSMENT of MJA 15/17

SCOPE OF ASSESSMENT		
Products/materials to be tested	**Type of test**	**Test methods**
		Subdivision of tablets Uniformity of dosage units (Ph. Eur. 2.9.40.)
	Others (please specify)	SDS page Western Blot (proteins + peptides)
Animal housing YES ☐/ NO X		

Remarks:
From the Audit Notification the following changes have been made:

- Ph. Eur. reference 2.2.60. replaced with 2.2.14. – the OMCL performs melting point by visual determination (*)
- GC-MS included in the scope of this MJA (**)