Co-funded by the European Union

EUROPEAN UNION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Co-funded and implemented by the Council of 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

Sciensano, Lab for Quality of Vaccines and Blood Products

Juliette Wytsmanstraat 14, 1050 Brussels, Belgium

Section audited: Unit Quality of Vaccines and Blood Products

has been audited in accordance with the EDQM instruction *IS07/02* 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 (23) 03 DEF*** and the Follow-up Report ***PA/PH/OMCL-QA (23) 26 DEF*** corresponding to the **MJA 01/23,** 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-191***

Strasbourg, 15/12/2023

Valid until: ***14 February 2027***

Dr Michael Wierer

Head of Medicines Division, DBO, EDQM

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 01/23

General Information

Laboratory audited	Sciensano, Lab for Quality of Vaccines and Blood Products
OMCL code	OMCL-BE_Sciensano-B
GEON Membership Status	Full member
Lab Address	Juliette Wytsmanstraat 14
Postal Code	1050
City	Bruxelles
Country	Belgium
Head of Service Quality of Vaccines and Blood Products	Geneviève Waeterloos
Head of Service Quality, (Bio)Safety and Environment	Patricia Cliquet
Contact person for the MJA	Geneviève Waeterloos
Contact e-mail	Geneviève.Waeterloos@sciensano.be
Date of MJA 01/23	7-9 February 2023
History of Assessments	MJA 09/18 Date: 9-11 October 2018 MJA 10/14 Date: 16-16 October 2014

Field of Activity

The key activities of the service Quality of Vaccines and blood products of Sciensano are:

- Batch release of vaccine plasma-derived medicinal products i.e. independent premarketing quality control of batches to assess the production consistency and conformity to the approved specifications;
- Advising during licensing;
- Advising during GMP inspections;
- Ad hoc regulatory activities;
- R&D projects (regulatory framework).

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 01/23

Scope of Assessment

Samples tested:

Chemicals

- ☐ Active Pharmaceutical Ingredients (API)
- ☐ Pharmaceutical finished dosage forms
- ☐ Pharmaceutical excipients
- ☐ Herbals

Biologicals

- ☑ Vaccines
  - ☑ a) Bacterial
  - ☑ b) Viral
- ☑ Blood/plasma derivatives
- ☐ Biotechnology products
- ☑ VIMP (veterinary immunological medicinal
- ☐ Other biological products (please specify)

Animal housing ☑ Yes ☐ No

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
for biological samples		
Antigenicity, UV-Vis absorption spectrophotometry	2.2.25.	SOP 42/III.60, SOP 42/III.75, SOP 42/III.76
Assay of diphtheria vaccine adsorbed, Biological assays	2.7.6.	SOP 42/III.12, SOP 42/III.16
Assay of hepatitis A vaccine, Enzyme-linked immunosorbent assay (ELISA)	2.7.14.	SOP 42/III.01
Assay of hepatitis B vaccine rDNA, Enzyme-linked immunosorbent assay (ELISA)	2.7.15.	SOP 42/III.03, SOP 42/III.41
Assay of immunoglobulins, Enzyme-linked immunosorbent assay (ELISA)	2.7.1.	SOP 42/III.01, SOP 42/III.03, SOP 42/III.07, SOP 42/III.28, SOP 42/III.41, SOP 42/III.56, SOP 42/III.57, SOP 42/III.61, SOP 42/III.62, SOP 42/III.70, SOP 42/III.72, SOP 42/III.74
Assay of tetanus vaccine (absorbed), Challenge test (method A and B)	2.7.8.	SOP 42/III.13, SOP 42/III.14
Bacterial endotoxins, Method D (Chromogenic kinetic method), Bacterial endotoxins	2.6.14.	SOP 42/III.25/F, will be replaced in 2023 by 2.6.32 Test for bacterial endotoxins using recombinant factor C
Capillary gel electrophoresis	2.2.47.	SOP 42/III.112

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 01/23

Test item*/Test methods	Ph.Eur. Chapter/ Monograph#	Additional references / comments
Cell-culture/cell-line based assay/vaccine titration, Assay (bio)		SOP 42/III.10, SOP 42/III.19, SOP 42/III.21, SOP 42/III.22, SOP 42/III.109
Clarity and degree of opalescence of liquids, Visual	2.2.1.	SOP 42/III.26
Contrôle du titre des vaccins vivants dirigés contre la Maladie de Newcastle	0450; PA/PH/OMCL (02) 4 DEF 2 CORR ; PA/PH/OMCL (14) 127 DEF	SOP VAC/ANA/14
Degree of coloration of liquids	2.2.2.	SOP 42/III.26
Determination of total mRNA content & percentage of mRNA encapsulation in liposome		SOP 42.III.37
Enzyme-linked immunosorbent assay (ELISA), Identification test (bio)		
Free Polyribosylribitolphosphate (PRP), HPLC	07/2018:1219 04/2016:2622	SOP 42/III.52
Immunochemical methods	2.7.1.	SOP 42/III.45, SOP 42/III.55
Immunodiffusion (ID), Immunoprecipitation method		SOP 42/III.45, SOP 42/III.55
Infectious unit by Q-PCR based potency assay (QPA)		SOP 42/III.109
Liquid chromatography, Fluorescence (FLD)	2.2.29.	SOP 42/III.71
Liquid chromatography, Pulse amperometric (PAD)	2.2.29.	SOP 42/III.52
Liquid chromatography, Refractive index (RI)	2.2.29.	SOP 42/III.84
Molecular mass distribution in dextrans		SOP 42/III.84
Particulate contamination-visible particles	2.9.20.	SOP 42/III.26, SOP 42/III.40
Polymerase chain reaction (PCR), Nucleic acid amplification techniques	2.6.21.	SOP 42/III.38, SOP 42/III.65, SOP 42/III.66, SOP 42/III.108
Potentiometric determination of pH	2.2.3.	SOP 42/III.26
Protein in polysaccharide vaccines	2.5.16.	SOP 42/III.59
Thrombin activity, measuring coagulation time with fibrinogene		SOP 42/III.67
Titrage des vaccins: IBR live vaccins	monograph 0696	SOP VAC/ANA/30
Total protein, Method 2 (Lowry assay)	2.5.33.	SOP 42/III.59

* - whenever applicable

- Chapter/Monograph in force at the moment of the Audit

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

FINAL SCOPE OF ASSESSMENT OF MJA 01/23

Remarks

During the audit, it was agreed to:

1) remove the method size-exclusion chromatography (Ph. Eur. 2.2.30 and SOP 42/III.31) from the scope of the audit, since it is still in validation phase and no batch data were available,

2) remove the reference to Ph. Eur. 2.2.39 for the molecular mass distribution in dextrans, since this method is performed following the procedure described in the manufacturer dossier (SOP 42/III.84).