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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, Biological Standardisation Unit

14 rue Juliette Wytsman, 1050 Brussels, Belgium

Section audited: Vaccines control, Plasma-derived medicinal products

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 (14) 19 DEF*** and the Follow-up Report ***PA/PH/OMCL-QA (15) 15 DEF*** corresponding to the **MJA 10/14,** 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-094***

Strasbourg, 7 October 2015

Valid until: ***April 2019***

pp

Dr. Karl-Heinz Buchheit

Head of DBO, EDQM

SCOPE OF ASSESSMENT of MJA 10/14 Page 1 of 3

Field of activity: The OMCL is engaged in three main activities in the human field:

- Official Control Batch Release (OCABR) of vaccines and plasma derivatives.
- Advising during licensing and
- Advising during GMP Inspection (for vaccines, plasma derivatives and rDNA biological medicinal products), following the request from the Federal Agency for Medicines and Health Products (FAMHP).

Name of the OMCL: **Scientific Institute of Public Health**
Biological Standardisation Unit

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History of assessments:

- **MJA 10/14** **Date: 14 to 16 October 2014**
- MJA 01/09 Date: 24 to 26 March 2009
- MJA 02/01 Date: 26 to 27 March 2001

SCOPE OF ASSESSMENT			
Products/materials to be tested	**Type of test**	**Test methods** (where applicable, reference should be made to the corresponding Ph. Eur. General Method)	**Frequency of testing in the preceeding year**
Biologicals Vaccines ☒ a) Bacterial ☒ b) Viral ☒ Blood/plasma derivatives ☒ Biotechnology products ☐ VIMP (veterinary immunological medicinal products ☐ Other biological products ☒ (please specify)	Product-specific (potency tests etc.) **See Scope in Annex 1**		
Animal housing YES ☒/ NO ☐			

Remarks: n/a

Annex 1 – Scope of assessment (detailed list of test methods)

Product component	Release test(s) (*Type of tests*)	SOP nr	**Test Methods** (where applicable reference should be made to the corresponding Ph.Eur General Method).	**Frequency of testing the preceeding year**
				nr of runs (nr of batches)
Vaccines a) bacterial				
Pertussis (whole cell)	• Potency & identity: multiple dilution, B. pertussis intracerebral challenge test (Kendrick test) on mice versus in-house reference	42/III-06/N	Ph.Eur. 2.7.7 (Assay of Pertussis vaccine (whole cell)	8 (13)
	• Specific toxicity: Mouse Weight Gain test	42/III-35/N		4 (12)
Pertussis (acellular)	• Residual pertussis toxin: Histamin sensitising activity in mice	42/III-15/F-N	Ph.Eur. 2.6.33 (Residual Pertussis Toxin & Irreversibility of Pertussis Toxoid)	10 (151)
	• Endotoxin content: LAL	42/III-25/F	Ph.Eur. 2.6.14 - D (Chromogenic kinetic method)	40(532)
Meningococcus	• Identity & polysaccharide content : ELISA	42/III-54/F	Ph Eur : 2.7.1 (Immunochemical methods)	42 (24)
	• Endotoxin content: LAL	42/III-25/F	Ph.Eur. 2.6.14 - D (Chromogenic kinetic method)	40 (532)
Meningococcus (conjugate)	• Endotoxin content: LAL	42/III-25/F	Ph.Eur. 2.6.14 - D (Chromogenic kinetic method)	40 (532)
Haemophilus influenzae type B	• Identity, free polysaccharide content: ELISA on adsorbed vaccines	42/III-07/F	Ph Eur : 2.7.1 (Immunochemical methods)	72 (159)
	• Total Polysaccharide content: HPLC Dionex * FreePS Hiberix * FreePS Act-Hib * FreePS Hexaxim	42/III-52/F		58 (424)
	• Endotoxin content: LAL	42/III-25/F	Ph.Eur. 2.6.14 - D (Chromogenic kinetic method)	40 (532)
Pneumococcal polysaccharide monovalent bulk conjugate	• Protein content: Lowry	42 /III-59/F-N	Ph.Eur. 2.5.16 (protein in polysaccharide vaccines)	17 (97)
	• Polysaccharide content: Resorcinol	42/III-60/F-N		42 (157)
	• Free Polysaccharide content: ELISA–PS4	42/III-61/F	Ph Eur : 2.7.1 (Immunochemical methods)	22 (41)
	• Free Polysaccharide content: ELISA –PS18C	42/III-62/F	Ph Eur : 2.7.1 (Immunochemical methods)	48 (74)
Vaccines b) viral				
Hepatitis A	• Antigen content: ELISA versus in house reference	42/III-01/F	Ph.Eur. 2.7.1 (Immunochemical methods) Ph.Eur. 2.7.14 (Assay of Hepatitis A vaccine)	27 (72)
Hepatitis B	• MPL Content: GC	42/III-51/F		11 (33)
	• in-vitro ELISA test for HBsAg content versus in-house reference	42/III-03/F	Ph.Eur. 2.7.15 (Assay of Hepatitis B vaccine)	40 (180)
	• Purity and identity: PAGE * AgNO3 * Coommassie	42/III-05/F	Ph.Eur. 2.5.31 (electrophoresis)	31 (138)
Inactivated Poliomyelitis Vaccine (IPV)	• In-vitro ELISA test for D-antigen content versus in-house reference (GSK)	42/III-28F	Ph Eur : 2.7.1 (Immunochemical methods)	25 (69)
Human Papillomavirus	• Purity and identity: PAGE	42/III-05/F	Ph.Eur. 2.5.31 (electrophoresis)	8 (33)
	• in-vitro ELISA test for HPV antigen content versus in-house reference	42/III-57/F	Ph Eur : 2.7.1 (Immunochemical methods)	19 (27)
	• MPL Content: GC	42/III-51/F		see Hep B
Measles, Mumps, Rubella, Varicella	• Identity, potency and thermal stability: CCID50 assay	42/III-21/F		47 (88-Me), 49 (88-Mu), 28 (85-Ru)
Varicella	• Identity, potency and thermal stability: CCID50 assay	42/III-22/F		24 (56)
Polio monovalent bulk	• Neurovirulence test: Tg mice - clinical scoring	42/III-53/F	Ph.Eur. 2.6.19 (Test for Neurovirulence of Poliomyelitis vaccine oral)	8 (7)
Polio final lot	• Identity, potency and thermal stability: $CCID_{50}$ assay	42/III-10/F		25 (48)
Rotavirus	• Identity, potency and thermal stability: $CCID_{50}$ assay	42/III-19/F		25 (47)
Different vaccines as applicable	• Description/appearance	42/III-26/F	Ph.Eur. 2.2.1 (Clarity and degree of opalescence of liquids) Ph.Eur. 2.2.20 (particulate contamination: visible particles)	51 (751)
	• pH	42/III-26/F	Ph.Eur. 2.2.3 (Potentiomeric determination of pH)	17 (162)
Plasma-derived medicinal product				
Plasma pool	• *HCV RNA: NAT (temporary subcontracted to ANSM, Fr)*		Ph.Eur. 2.6.21 (NAT)	*January-October: 15 (120) - November-December ANSM: 43 batches*
	• Viral markers (HBsAg , anti-HIV1 & 2): MEIA	42/III-41/F		13 (188)
Albumin	• Appearance / Solubility: visual observation	42/III-40/F		30 (30)
	• Distribution of molecular size: HPLC	42/III-31/F	Ph.Eur. 2.2.30 (Size-Exclusion Chromatography)	18 (11)
	• Pre-kallikrein activator: kinetic measurement of OD vs BRP	42/III-34/F	Ph.Eur. 2.6.15 (PKA)	12 (20)
Immunoglobulin	• Appearance / Solubility: visual observation	42/III-40/F		2 (2)
	• Protein content: biuret	42/III-29/F	Ph.Eur. 2.5.33 (Total Protein) - Method 5	4 (2)
	• Distribution of molecular size: HPLC	42/III-31/F	Ph.Eur. 2.2.30 (Size-Exclusion Chromatography)	see albumin
Fibrin Sealant	• Appearance / Solubility Thrombin: visual observation	42/III-40/F		55 (55)
	• Appearance / Solubility Fibrinogen: visual observation	42/III-40/F		22 (22)
	• Stability Fibrinogen: visual observation	42/III-40/F		
	• Potency Thrombin: clotting time	42/III-67/F		23 (55)
	• Potency Fibrinogen: clottable protein: clotting assay - OD measurement vs in house reference	42/III-63/F		12 (22)
	• Potency Fibrinogen: total protein: OD measurement vs in house reference	42/III-64/F		10 (22)