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ATTESTATION

To whom it may concern:

I, Qualified Person, attest that for PUREVAX RCPCH (**L461279**) there are different manufacturing dates:

- One for the PUREVAX RCPCH: **28 AUGUST 2018**
- One for the diluent : **18 NOVEMBER 2017**

- One for the final product which associates PUREVAX RCPCH and diluent
(and is the date of packaging of final product) **22 NOVEMBER 2018**

The expiry date of this product is:

07 MARCH 2020

Lyon, 28 January 2019

Qualify Person
MERIAL Lyon


Dr Magali BENABEN
Substitute Deputy Qualified Person
Merial Lyon



CERTIFICATE OF ANALYSIS

PUREVAX RCPCH

COMMERCIAL LOT: L461279

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 18PCCP1E61

MANUFACTURING DATE: 28-Aug-2018

EXPIRY DATE: 07-Mar-2020

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	HOMOGENEOUS BEIGE PELLET	HOMOGENEOUS BEIGE PELLET	05-Sep-2018 05-Sep-2018
PH	10010	6.8 ≤ R ≤ 7.8 pH Unit	7.3 pH Unit	07-Sep-2018 07-Sep-2018
RESIDUAL MOISTURE	10020	0.5 ≤ R ≤ 3.5 %	1.7 %	07-Sep-2018 07-Sep-2018
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	10-Sep-2018 24-Sep-2018
MYCOPLASMIC STERILITY	11204	NO GROWTH	NO GROWTH	11-Sep-2018 09-Oct-2018
PANLEUCOPENIA VIRUS IDENTIFICATION	12055	R ≥ 2 Log(10)	>3.6 Log(10)	07-Sep-2018 13-Sep-2018
PARVOVIRUS COMPONENT IDENTIFICATION - HA	12315	HA AT pH 6,4, NO HA AT pH 7,3	HA AT pH 6,4, NO HA AT pH 7,3	13-Sep-2018 14-Sep-2018
VIRAL PURITY/INACTIVATION (ON BLENDING)	13020	NO CPE, NO HA AND NO HAD	NO CPE, NO HA AND NO HAD	13-Sep-2018 01-Oct-2018
PANLEUCOPENIA VIRUS TITRATION*	15351	3.5 ≤ R ≤ 5.2 Log10 CCID50/mL	4.4 Log10 CCID50/mL	07-Sep-2018 13-Sep-2018
HERPESVIRUS TITRATION	15352	5.5 ≤ R ≤ 6.2 Log10 CCID50/mL	5.9 Log10 CCID50/mL	07-Sep-2018 12-Sep-2018
CHLAMYDIA TITRATION	1645	3.7 ≤ R ≤ 5.0 Log10 EID50/mL	4.4 Log10 EID50/mL	10-Sep-2018 21-Sep-2018
CALICIVIRUS G1 IDENTIFICATION	2416	R > 0.2 OD Unit	1.5 OD Unit	13-Sep-2018 13-Sep-2018
CALICIVIRUS 431 IDENTIFICATION	2417	R > 0.2 OD Unit	1.4 OD Unit	13-Sep-2018 13-Sep-2018
CALICIVIRUS TITRATION	2418	2.15 ≤ R ≤ 3.30 ELISA Unit/mL	2.8 ELISA Unit/mL	13-Sep-2018 13-Sep-2018
HERPESVIRUS IDENTIFICATION	2454	SPECIFIC FLUORESCENCE	SPECIFIC FLUORESCENCE	08-Oct-2018 09-Oct-2018
CHLAMYDIA IDENTIFICATION	2481	POSITIVE FLUORESCENCE	POSITIVE FLUORESCENCE	10-Sep-2018 17-Sep-2018

* CALCULATION OF THE EXPIRY DATE

WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE COMPETENT AUTHORITIES

Signature / Function

Magali BENABEN
Deputy Head of Quality Control

CERTIFICATE OF ANALYSIS

PUREVAX RCPCH

COMMERCIAL LOT: L461279

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 17SRL0C41

MANUFACTURING DATE: 18-Nov-2017

EXPIRY DATE: 07-Mar-2020

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	CLEAR, COLOURLESS LIQUID	CLEAR, COLOURLESS LIQUID	27-Nov-2017 27-Nov-2017
VOLUME	10011	1.0 ≤ R ≤ 1.1 mL	1.0 mL	06-Dec-2017 06-Dec-2017
RESISTIVITY	10018	R ≥ 0.04 Mohm.cm	0.15 Mohm.cm	06-Dec-2017 06-Dec-2017
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	08-Dec-2017 22-Dec-2017
RESIDUE ON EVAPORATION	111	R ≤ 0.004 %	0.003 %	07-Dec-2017 07-Dec-2017
CHLORIDES	125	R ≤ 10 ppm	<10 ppm	06-Dec-2017 06-Dec-2017
ACIDITY	1485	R ≤ 0.1 mL NaOH 0.01 N	0.0 mL NaOH 0.01 N	06-Dec-2017 06-Dec-2017
ALKALINITY	1485	R ≤ 0.15 mL HCL 0.01 N	<0.15 mL HCL 0.01 N	06-Dec-2017 06-Dec-2017
ENDOTOXINS	18053	R ≤ 0.25	<0.005	29-Nov-2017 29-Nov-2017
OXIDISABLE SUBSTANCES	192	NEGATIVE REACTION	NEGATIVE REACTION	06-Dec-2017 06-Dec-2017
AMMONIUM	296	R ≤ 1 ppm	<1 ppm	06-Dec-2017 06-Dec-2017
CALCIUM AND MAGNESIUM	524	PURE BLUE COLOUR	PURE BLUE COLOUR	07-Dec-2017 07-Dec-2017
NITRATES	525	R ≤ 0.5 ppm	<0.5 ppm	07-Dec-2017 07-Dec-2017
SULPHATES	66	R ≤ 0.5 ppm	<0.5 ppm	06-Dec-2017 06-Dec-2017
HEAVY METALS	67	R ≤ 0.1 ppm	<0.1 ppm	07-Dec-2017 07-Dec-2017

**WE CERTIFY THIS PRODUCT MEETS THE REQUIREMENTS OF THE
COMPETENT AUTHORITIES**

Signature / Function

Magali BENABEN
Deputy Head of Quality Control

