



RUSSIAN FEDERATION
26037374

Site de Lyon-Porte-des-Alpes
Rue de l'Aviation
69800 Saint-Priest - France
Tél.: +33 (0) 4 72 72 30 00
Fax: +33 (0) 4 72 72 34 91

ATTESTATION

To whom it may concern:

I, Qualified Person, attest that for PUREVAX RCPCH (**L480933**) there are different manufacturing dates:

- One for the PUREVAX RCPCH: **22 MARCH 2020**
- One for the diluent : **09 MARCH 2020**

- One for the final product which associates PUREVAX RCPCH and diluent
(and is the date of packaging of final product) **27 JULY 2020**

The expiry date of this product is: **02 OCTOBER 2021**

Lyon, 10 August 2020

Qualify Person
MERIAL Lyon

Dr Magali BENABEN
Substitute Deputy Qualified Person
Merial Lyon

CERTIFICATE OF ANALYSIS

PUREVAX RCPCH

COMMERCIAL LOT: L480933

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 20SRL0P11

MANUFACTURING DATE: 09-Mar-2020

EXPIRY DATE: 02-Oct-2021

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	CLEAR, COLOURLESS LIQUID	CLEAR, COLOURLESS LIQUID	18-Mar-2020 18-Mar-2020
VOLUME	10011	1.0 <= R <= 1.1 mL	1.1 mL	24-Mar-2020 24-Mar-2020
RESISTIVITY	10018	R >= 0.04 Mohm.cm	0.19 Mohm.cm	24-Mar-2020 24-Mar-2020
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	30-Mar-2020 14-Apr-2020
RESIDUE ON EVAPORATION	111	R <= 0.004 %	0.001 %	24-Mar-2020 24-Mar-2020
CHLORIDES	125	R <= 10 ppm	<10 ppm	24-Mar-2020 24-Mar-2020
ACIDITY	1485	R <= 0.1 mL NAOH 0.01 N	<0.10 mL NAOH 0.01 N	24-Mar-2020 24-Mar-2020
ALKALINITY	1485	R <= 0.15 mL HCL 0.01 N	0 mL HCL 0.01 N	24-Mar-2020 24-Mar-2020
ENDOTOXINS	18053	R <= 0.25	<0.005	18-Mar-2020 18-Mar-2020
OXIDISABLE SUBSTANCES	192	NEGATIVE REACTION	NEGATIVE REACTION	24-Mar-2020 24-Mar-2020
AMMONIUM	296	R <= 1 ppm	<1 ppm	24-Mar-2020 24-Mar-2020
CALCIUM AND MAGNESIUM	524	PURE BLUE COLOUR	PURE BLUE COLOUR	24-Mar-2020 24-Mar-2020
NITRATES	525	R <= 0.5 ppm	<0.5 ppm	24-Mar-2020 24-Mar-2020
SULPHATES	66	R <= 0.5 ppm	<0.5 ppm	24-Mar-2020 24-Mar-2020
HEAVY METALS	67	R <= 0.1 ppm	<0.1 ppm	24-Mar-2020 24-Mar-2020

**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: L480933

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 20PCCP1H91

MANUFACTURING DATE: 22-Mar-2020

EXPIRY DATE: 02-Oct-2021

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	HOMOGENEOUS BEIGE PELLET	HOMOGENEOUS BEIGE PELLET	30-Mar-2020 30-Mar-2020
PH	10010	6.8 <= R <= 7.8 pH Unit	7.2 pH Unit	14-Apr-2020 14-Apr-2020
RESIDUAL MOISTURE	10020	0.5 <= R <= 3.5 %	1.4 %	14-Apr-2020 14-Apr-2020
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	03-Apr-2020 17-Apr-2020
MYCOPLASMIC STERILITY	11204	NO GROWTH	NO GROWTH	31-Mar-2020 28-Apr-2020
PANLEUCOPENIA VIRUS IDENTIFICATION	12055	R >= 2 Log(10)	>2.5 Log(10)	09-Apr-2020 15-Apr-2020
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	15-Apr-2020 16-Apr-2020
VIRAL PURITY/INACTIVATION (ON BLENDING)	13020	NO CPE, NO HA AND NO HAD	NO CPE, NO HA AND NO HAD	02-Apr-2020 21-Apr-2020
PANLEUCOPENIA VIRUS TITRATION	15351	3.5 <= R <= 5.2 Log10 CCID50/dose	4.4 Log10 CCID50/dose	09-Apr-2020 15-Apr-2020
HERPES VIRUS TITRATION*	15352	5.5 <= R <= 6.2 Log10 CCID50/dose	5.8 Log10 CCID50/dose	02-Apr-2020 22-Apr-2020
CHLAMYDIA TITRATION	1645	3.7 <= R <= 5.0 Log(10) EID50/dose	4.7 Log(10) EID50/dose	06-Apr-2020 17-Apr-2020
CALICIVIRUS G1 IDENTIFICATION	2416	R > 0.2 OD Unit	1.4 OD Unit	10-Apr-2020 10-Apr-2020
CALICIVIRUS 431 IDENTIFICATION	2417	R > 0.2 OD Unit	1.3 OD Unit	10-Apr-2020 10-Apr-2020
CALICIVIRUS TITRATION	2418	2.15 <= R <= 3.30 ELISA Unit/dose	2.62 ELISA Unit/dose	10-Apr-2020 10-Apr-2020
HERPESVIRUS IDENTIFICATION	2454	SPECIFIC FLUORESCENCE	SPECIFIC FLUORESCENCE	20-Apr-2020 21-Apr-2020
CHLAMYDIA IDENTIFICATION	2481	POSITIVE FLUORESCENCE	POSITIVE FLUORESCENCE	16-Apr-2020 23-Apr-2020

* CALCULATION OF THE EXPIRY DATE

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

Signature / Function

10-Aug-2020
Page 1 of 1



Magali BENABEN
Deputy Head of Quality Control