



RUSSIAN FEDERATION
26037374

Site de Lyon-Porte-des-Alpes
Rue de l'Aviation
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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



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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

10-Aug-2020
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