



RUSSIAN FEDERATION
26035721

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 (**L478723**) there are different manufacturing dates:

- One for the PUREVAX RCPCH: **07 JANUARY 2020**
- One for the diluent: **09 JANUARY 2020**

- One for the final product which associates PUREVAX RCPCH and diluent
(and is the date of packaging of final product) **22 MAY 2020**

The expiry date of this product is: **16 JULY 2021**

Lyon, 12 June 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: L478723

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 20SRL0N81

MANUFACTURING DATE: 09-Jan-2020

EXPIRY DATE: 16-Jul-2021

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	CLEAR, COLOURLESS LIQUID	CLEAR, COLOURLESS LIQUID	14-Jan-2020 14-Jan-2020
VOLUME	10011	1.0 <= R <= 1.1 mL	1.06 mL	03-Feb-2020 03-Feb-2020
RESISTIVITY	10018	R >= 0.04 Mohm.cm	0.12 Mohm.cm	03-Feb-2020 03-Feb-2020
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	17-Jan-2020 31-Jan-2020
RESIDUE ON EVAPORATION	111	R <= 0.004 %	0 %	03-Feb-2020 03-Feb-2020
CHLORIDES	125	R <= 10 ppm	<10 ppm	03-Feb-2020 03-Feb-2020
ACIDITY	1485	R <= 0.1 mL NAOH 0.01 N	<0.1 mL NAOH 0.01 N	03-Feb-2020 03-Feb-2020
ALKALINITY	1485	R <= 0.15 mL HCL 0.01 N	0 mL HCL 0.01 N	03-Feb-2020 03-Feb-2020
ENDOTOXINS	18053	R <= 0.25	<0.005	15-Jan-2020 15-Jan-2020
OXIDISABLE SUBSTANCES	192	NEGATIVE REACTION	NEGATIVE REACTION	03-Feb-2020 03-Feb-2020
AMMONIUM	296	R <= 1 ppm	<1 ppm	03-Feb-2020 03-Feb-2020
CALCIUM AND MAGNESIUM	524	PURE BLUE COLOUR	PURE BLUE COLOUR	03-Feb-2020 03-Feb-2020
NITRATES	525	R <= 0.5 ppm	<0.5 ppm	03-Feb-2020 03-Feb-2020
SULPHATES	66	R <= 0.5 ppm	<0.5 ppm	03-Feb-2020 03-Feb-2020
HEAVY METALS	67	R <= 0.1 ppm	<0.1 ppm	03-Feb-2020 03-Feb-2020

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

Signature / Function

Magali BENABEN
Deputy Head of Quality Control



11-Jun-2020
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