

CERTIFICATE OF ANALYSIS

PUREVAX RCPCH

COMMERCIAL LOT: L478719

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 19PCCP1H31

MANUFACTURING DATE: 08-Dec-2019

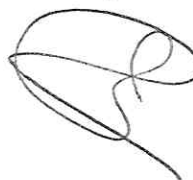
EXPIRY DATE: 19-Jun-2021

TESTS	TECHNIQUES	THRESHOLDS	RESULTS	START / END DATES
APPEARANCE	10001	HOMOGENEOUS BEIGE PELLET	HOMOGENEOUS BEIGE PELLET	17-Dec-2019 17-Dec-2019
PH	10010	6.8 <= R <= 7.8 pH Unit	7.2 pH Unit	08-Jan-2020 08-Jan-2020
RESIDUAL MOISTURE	10020	0.5 <= R <= 3.5 %	1.6 %	08-Jan-2020 08-Jan-2020
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	20-Dec-2019 03-Jan-2020
MYCOPLASMIC STERILITY	11204	NO GROWTH	NO GROWTH	24-Dec-2019 21-Jan-2020
PANLEUCOPENIA VIRUS IDENTIFICATION	12055	R >= 2 Log(10)	3 Log(10)	20-Dec-2019 26-Dec-2019
PARVOVIRUS COMPONENT IDENTIFICATION - HA VIRAL	12315	HA AT pH 6,4, NO HA AT pH 7,3	HA AT pH 6,4, NO HA AT pH 7,3	26-Dec-2019 27-Dec-2019
PURITY/INACTIVATION (ON BLENDING)	13020	NO CPE, NO HA AND NO HAD	NO CPE, NO HA AND NO HAD	12-Dec-2019 31-Dec-2019
PANLEUCOPENIA VIRUS TITRATION	15351	3.5 <= R <= 5.2 Log10 CCID50/dose	4.4 Log10 CCID50/dose	20-Dec-2019 26-Dec-2019
HERPES VIRUS TITRATION	15352	5.5 <= R <= 6.2 Log10 CCID50/dose	6.0 Log10 CCID50/dose	02-Jan-2020 04-Feb-2020
CHLAMYDIA TITRATION*	1645	3.7 <= R <= 5.0 Log(10) EID50/dose	4.2 Log(10) EID50/dose	19-Dec-2019 30-Dec-2019
CALICIVIRUS G1 IDENTIFICATION	2416	R > 0.2 OD Unit	1.5 OD Unit	20-Dec-2019 20-Dec-2019
CALICIVIRUS 431 IDENTIFICATION	2417	R > 0.2 OD Unit	1.3 OD Unit	20-Dec-2019 20-Dec-2019
CALICIVIRUS TITRATION	2418	2.15 <= R <= 3.30 ELISA Unit/dose	2.65 ELISA Unit/dose	20-Dec-2019 20-Dec-2019
HERPESVIRUS IDENTIFICATION	2454	SPECIFIC FLUORESCENCE	SPECIFIC FLUORESCENCE	23-Dec-2019 24-Dec-2019
CHLAMYDIA IDENTIFICATION	2481	POSITIVE FLUORESCENCE	POSITIVE FLUORESCENCE	19-Dec-2019 26-Dec-2019

* 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



11-Jun-2020
Page 1 of 1



RUSSIAN FEDERATION
26035721

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 (**L478719**) there are different manufacturing dates:

- One for the PUREVAX RCPCH: **08 DECEMBER 2019**
- 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) **20 MAY 2020**

The expiry date of this product is: **19 JUNE 2021**

Lyon, 11 June 2020

Qualify Person
MERIAL Lyon

Dr Magali BENABEN
Substitute Deputy Qualified Person
Merial Lyon

