

RUSSIAN FEDERATION
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CERTIFICATE OF ANALYSIS

RABISIN

COMMERCIAL LOT: L478053

STORAGE BETWEEN: 2°C-8°C

PRESENTATION: Bottle of 1 dose

FILLED PRODUCT LOT NUMBER: 19RBNS0K21

MANUFACTURING DATE: 14-Sep-2019

EXPIRY DATE: 14-Sep-2022*

TESTS	TECHNIQUES	THRESHOLDS	RÉSULTS	START / END DATES
APPEARANCE	10001	HOMOGENEOUS AND OPALESCENT SUSPENSION	HOMOGENEOUS AND OPALESCENT SUSPENSION	23-Sep-2019 23-Sep-2019
PH	10010	7.2 <= R <= 8.2 pH Unit	8.0 pH Unit	01-Oct-2019 01-Oct-2019
VOLUME	10011	1.0 <= R <= 1.1 mL	1.0 mL	01-Oct-2019 01-Oct-2019
ALUMINE ASSAY	10040	1.4 <= R <= 2.0 mg/mL	1.7 mg/mL	26-Sep-2019 27-Sep-2019
BACTERIAL AND FUNGIC STERILITY	11000	NO GROWTH	NO GROWTH	26-Sep-2019 10-Oct-2019
IDENTITY ON 10 MICE	12705	R >= 4 Healthy animals	9 Healthy animals	26-Sep-2019 13-Oct-2019
RABIES INACTIVATION TEST ON MICE	14307	R= 10 Healthy animals	10 Healthy animals	30-Oct-2019 20-Nov-2019
SPECIFIC SAFETY / 2 DOGS	18330	R= 2 Healthy animals	2 Healthy animals	24-Sep-2019 15-Oct-2019
POTENCY ON MICE*	19319	R >= 1 IU/dose	30.18 IU/dose	08-Jan-2020 05-Feb-2020

* EXPIRY DATE CALCULATED USING THE FORMULATION DATE

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

Signature / Function

Véronique SARRÈRE
Deputy Head of Quality Control

14-May-2020
Page 1 of 1