Certificate of Analysis

Product: Porcilis PCV 1x100ds (200ml) 575

Batch: B709A01

Country Romania

Sales Order Number

1111929281 / 10

Delivery Number:

1214815519 / 900002

MSD

INTERVET INTERNATIONAL BV Wim de Körverstraat 35

P.O. Box 31, 5830 AA BOXMEER

NETHERLANDS

Material Number

028857

Product Type

Dosage per Container

Inactivated Vaccines

100 Doses

Start date of Shelf Life

Expiry Date

02-Feb-2022

28-Feb-2025

Storage Conditions

2-8°C

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Regulation (EU) 2019/6. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name:

H. van. Zuijlen

Function:

DE CED onco

Date:

Z D SEP ZUZZ

Signature

Qualified Person

Printed: 23-Sep-2022 10:33:32 Profile: Z012 8-601514_EU 1

Profile Z012 8-601514_EU Form Z1QM_QCERT_10 Trade register 's-Hertogenbosch 16028015

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Certificate of Analysis

Product: Porcilis PCV 1x100ds (200ml) 575 Batch: B709A01

Final Batch Testing Finished Product

Date on	Date off	Test Results
27-Jan-2022	17-Feb-2022	Sterility Tested according to Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
02-Feb-2022	03-Feb-2022	Antigenic mass AlphaLISA Result: 2532 AU/mL Threshold ≥ 1860 AU/mL Conclusion: Passed
		Result Identity conform Threshold Identity conform Conclusion. Passed
07-Feb-2022	07-Feb-2022	PH Tested according to: Ph. Eur. 2.2.3 Result: 6.5 Threshold: $6.0 \le X \le 7.5$ Conclusion. Passed
07-Feb-2022	07-Feb-2022	D,L alpha Tocopherol Acetate Result: 12.5 mg/mL Threshold: 11.8 ≤ X ≤ 13.2 mg/mL Conclusion: Passed
09-March-2022	09-March-2022	Mineral oil assay Result: 177 mg/mL Threshold: 155 ≤ X ≤ 191 mg/mL Conclusion: Passed
25-Jan-2022	25-Jan-2022	Appearance Result Conform Threshold Conform Conclusion Passed

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