

Certificate of Analysis

Product: **Porcilis PCV M Hyo 1x200ml 575**
Batch: **D070A02**

Country: **Romania**

Sales Order Number: **1111889990 / 10**

Delivery Number: **1214815519 / 900001**



Material Number:

140795

Product Type:

Inactivated Vaccines

Dosage per Container

100 Doses

Start date of Shelf Life:

26-Oct-2021

Expiry Date:

Oct-2023

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:

K. De Moor

Function:

Date:

23 SEP 2022

Signature:

Qualified Person

A handwritten signature in black ink, appearing to read "K. De Moor", written over a horizontal line.

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Final Batch Testing Finished Product

INTERVET INTERNATIONAL BV
Wim de Körverstraat 35
P.O. Box 31, 5830 AA BOXMEER
NETHERLANDS



| <u>Date on</u> | <u>Date off</u> | <u>Test Results</u> |
|----------------|-----------------|---|
| 26-Oct-2021 | 16-Nov-2021 | <u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and Ph. Eur. 0062 Result: No growth Threshold: No growth Conclusion: Passed |
| 17-Nov-2021 | 17-Nov-2021 | <u>Potency PCV2</u> Result: 2984 AU/mL Threshold: ≥ 1414 AU/mL Conclusion: Passed |
| 17-Nov-2021 | 17-Nov-2021 | <u>Identity PCV2</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed |
| 26-Oct-2021 | 29-Oct-2021 | <u>Potency M. hyo</u> Result: 3.60 RP Threshold: 2.69 - 6.29 RP Conclusion: Passed |
| 26-Oct-2021 | 29-Oct-2021 | <u>Identity M. hyo</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed |
| 03-Nov-2021 | 03-Nov-2021 | <u>Viscosity</u> Result: 5 mPa*s Threshold: $3 \leq X \leq 10$ mPa*s Conclusion: Passed |
| 22-Oct-2021 | 22-Oct-2021 | <u>pH</u> Result: 6.7 Threshold: $6.2 \leq X \leq 7.5$ Conclusion: Passed |
| 28-Oct-2021 | 28-Oct-2021 | <u>Aluminium</u> Result: 0.96 mg/mL Threshold: $0.82 \leq X \leq 1.20$ mg/mL Conclusion: Passed |
| 25-Oct-2021 | 08-Nov-2021 | <u>Stability of emulsion</u> Result: No phase separation Threshold: No phase separation Conclusion: Passed |
| 25-Oct-2021 | 25-Oct-2021 | <u>Appearance after shaking</u> Result: Conform Threshold: Conform Conclusion: Passed |