

Certificate of Analysis

Product: Porcilis PCV 1x100ds (1x200ml) 296
Batch: B079A01

Country: **Russian Fed.**

Sales Order Number: **1105525305 / 10**
Delivery Number: **1207058364 / 900001**

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



Material Number:
028758

Product Type: **Inactivated Vaccines** Dosage per Container: **100 Doses**

Start date of Shelf Life: **18-Dec-2017** Expiry Date: **Dec-2020**

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 Directive 2001/82/EC as amended. 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:

Function:

Date:

Signature:

A. van Drunen

16 FEB 2018

A handwritten signature in blue ink, appearing to read 'A. van Drunen', written over a faint blue circular stamp.

Qualified Person

Certificate of Analysis

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Final Batch Testing Finished Product

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<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
22-Nov-2017	13-Dec-2017	<u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
18-Dec-2017	15-Jan-2018	<u>Potency using chickens</u> Tested according to: Ph. Eur. 0962 Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency PCV</u> Result: 6.3 Log 2 Threshold: ≥ 4.5 Log 2 Conclusion: Passed
		<u>Identity</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
30-Nov-2017	14-Dec-2017	<u>Inactivation</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed
20-Nov-2017	20-Nov-2017	<u>pH</u> Tested according to: Ph. Eur. 2.2.3 Result: 6.4 Threshold: 6.0 - 7.5 Conclusion: Passed
		<u>D,L alpha Tocopherol Acetate</u> Result: 12.4 mg/mL Threshold: 11.8 - 13.2 mg/mL Conclusion: Passed
15-Nov-2017	15-Nov-2017	<u>Appearance</u> Result: Conform Threshold: Conform Conclusion: Passed