

Certificates of Analysis

Product: Porcilis Ery+Parvo 1x25ds (50ml) 296
Batch: A246A01

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



Country: **Russian Fed.**

Sales Order Number: **1105525267 / 10**

Delivery Number: **1206980106 / 900006**

Material Number:
118219

Product Type: **Inactivated Vaccines** Dosage per Container: **25 Doses**

Start date of Shelf Life: **08-Aug-2017** Expiry Date: **Aug-2019**

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: **A. van Drunen**

Function:

Date: **22 JAN 2018**

Signature: 

Qualified Person

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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>
04-Aug-2017	25-Aug-2017	<u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
25-Aug-2017	12-Sep-2017	<u>Inactivation</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed
08-Aug-2017	08-Aug-2017	<u>Antigen Content (PPV)</u> Result: 548 EU/mL Threshold: ≥ 276 EU/mL Conclusion: Passed
		<u>Identity PPV</u> Tested according to: Ph. Eur. 0965 Result: Identity conform Threshold: Identity conform Conclusion: Passed
08-Aug-2017	05-Sep-2017	<u>Potency using mice</u> Tested according to: Ph. Eur. 0064 Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency Erysipelas</u> Result: 3.3 RP Threshold: ≥ 1.0 RP Conclusion: Passed
		<u>Identity Erysipelas</u> Tested according to: Ph. Eur. 0064 Result: Identity conform Threshold: Identity conform Conclusion: Passed
09-Aug-2017	06-Sep-2017	<u>Extraneous agents using pigs</u> Tested according to: Ph. Eur. 0064 and 0965 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
02-Aug-2017	02-Aug-2017	<u>pH</u> Tested according to: Ph. Eur. 2.2.3 Result: 7.0 Threshold: 6.0 - 8.0 Conclusion: Passed

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<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
15-Aug-2017	15-Aug-2017	<u>D,L alpha Tocopherol Acetate</u> Result: 74.8 mg/mL Threshold: 71.3 - 78.8 mg/mL Conclusion: Passed
16-Aug-2017	16-Aug-2017	<u>Free formaldehyde</u> Tested according to: Ph. Eur. 2.4.18. Result: 0.04 % Threshold: 0.02 - 0.05 % Conclusion: Passed
24-Aug-2017	24-Aug-2017	<u>Macroscopical appearance of vaccine</u> Result: Conform Threshold: Conform Conclusion: Passed