

Certificate of Analysis

Product: **Porcilis ColiClos 1x25ds 296**
Batch: **A056A02**



Country: **Russian Fed.**

Sales Order Number: **1105047322 / 10**
Delivery Number: **1206309061 / 900002**

Material Number:
130221

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

Start date of Shelf Life: **26-Sep-2016** Expiry Date: **Sep-2018**

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: **A. van Drunen**

Date:

Signature: **19 MAY 2017** 

Qualified Person

Certificate of Analysis

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Final Batch Testing Finished Product



<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
13-Oct-2016	03-Nov-2016	<u>Sterility</u> Result: No growth Threshold: No growth Conclusion: Passed
26-Sep-2016	24-Oct-2016	<u>Potency using mice</u> Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency K88ab (EIA)</u> Result: 12.5 Log 2 Threshold: ≥ 9.3 Log 2 Conclusion: Passed
		<u>Identity K88ab</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
		<u>Potency K88ac (EIA)</u> Result: 10.7 Log 2 Threshold: ≥ 6.5 Log 2 Conclusion: Passed
		<u>Identity K88ac</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
		<u>Potency K99 (EIA)</u> Result: 8.6 Log 2 Threshold: ≥ 7.5 Log 2 Conclusion: Passed
		<u>Identity K99</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
		<u>Potency 987p (EIA)</u> Result: 9.3 Log 2 Threshold: ≥ 7.4 Log 2 Conclusion: Passed
		<u>Identity 987p</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed

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NETHERLANDS



<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
		<u>Potency LT (EIA)</u> Result: 11.1 Log 2 Threshold: ≥ 10.5 Log 2 Conclusion: Passed
		<u>Identity LT</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
05-Dec-2016	10-Dec-2016	<u>Potency using rabbits</u> Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency Cl. perfringens</u> Result: 77 IU/mL Threshold: ≥ 10 IU/mL Conclusion: Passed
10-Oct-2016	10-Oct-2016	<u>Endotoxin</u> Tested according to: Ph. Eur. 2.6.14 Result: $5E+05$ IU/dose Threshold: $\leq 2.4E+06$ IU/dose Conclusion: Passed
04-Oct-2016	04-Oct-2016	<u>D,L alpha Tocopherol Acetate</u> Result: 74.9 mg/mL Threshold: 67.5 - 82.5 mg/mL Conclusion: Passed
23-Sep-2016	23-Sep-2016	<u>pH</u> Tested according to: Ph. Eur. 2.2.3 Result: 6.8 Threshold: 6.0 - 8.0 Conclusion: Passed
15-Sep-2016	15-Sep-2016	<u>Appearance</u> Result: Conform Threshold: Conform Conclusion: Passed