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MSD Animal Health

Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

Antigen containing component:

Trade name:	**Porcilis PCV M Hyo**
Marketing authorisation number:	
Target species:	**Pigs**
Total number of containers in this batch:	**18 343**
Number of containers the release is applied for:	**18 343**
Number of doses per container:	**50**
Number of samples for the competent authority:	-
Date of expiry:	**Jan-2017**
Name and address of Marketing Authorisation Holder:	**Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer THE NETHERLANDS, represented by the local company**

16-Mar-2015/cc
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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Porcine circo virus type 2 and Mycoplasma hyopneumoniae vaccine for pigs(inactivated)**
Batch number of finished product:	**C159A01**
Batch number of final bulk:	**C159**
Pharmaceutical form of finished product:	**Emulsion for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**14-Jan-2015**
Storage temperature:	**2-8 °C**
Name and address of manufacturer:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**
Name and address of the batch release site:	**Intervet International B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **NEDERLAND**

CERTIFICATION BY THE MANUFACTURER

I herewith certify that concerned batch was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended.

Name: S.T.M. Verstegen
Function: Qualified Person
Date: 20 MAR 2015
Signature: .....

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
21-Jan-2015	11-Feb-2015	**Sterility (312)** Tested according to Ph.Eur.0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
04-Feb-2015	06-Feb-2015	**Potency PCV2 (305)** Result: 3229 AU/ml Threshold: ≥ 1414 AU/ml Conclusion: Passed
		Identity PCV2 (305) Result: Identity conform Threshold: Identity conform Conclusion: Passed
22-Jan-2015	02-Feb-2015	**Potency M hyo (306)** Result: 5.53 RPU Threshold: 2.69 - 6.29 RPU Conclusion: Passed
		Identity M hyo (306) Result: Identity conform Threshold: Identity conform Conclusion: Passed
30-Jan-2015	30-Jan-2015	**Viscosity (309)** Tested according to Ph.Eur. 2.2.10 Result: 5 mPa.s Threshold: 3 - 10 mPa.s Conclusion: Passed
23-Jan-2015	23-Jan-2015	**pH (304)** Tested according to Ph.Eur. 2.2.3 Result: 6.7 Threshold: 6.2 - 7.5 Conclusion: Passed

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FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
21-Jan-2015	21-Jan-2015	**Aluminum contents (307)** Tested according to Ph.Eur. 2.5.13 Result: 0.99 mg/ml Threshold: 0.82 - 1.20 mg/ml Conclusion: Passed
22-Jan-2015	05-Feb-2015	**Stability of emulsion (308)** Result: No phase separation Threshold: No phase separation Conclusion: Passed
22-Jan-2015	22-Jan-2015	**Appearance after shaking (311)** Result: Homogeneous white to nearly white Threshold: Homogeneous white to nearly white Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
Antigen	See composition table	Burgwedel Biotech GmbH, Germany
Bulk vaccin	See blending	Burgwedel Biotech GmbH, Germany
Filled product	See filling	Burgwedel Biotech GmbH, Germany

STARTING MATERIALS:

Bacterial seed lots:
Master seed material: **Mycoplasma hyopneumoniae strain ATCC# 25934**
MS-batch number: **19022-001**
Date of last testing: **28-Dec-2004**

Working seed material: **Mycoplasma hyopneumoniae strain ATCC# 25934**
WS-batch number: **15L12**
Date of last testing: **16-Dec-2014**

Virus seed lots:
Master seed material: **BacPCV2-Orf2**
MS-batch number: **98-99**
Date of last testing: **17-Oct-2006**

Working seed material: **BacPCV2-Orf2**
WS-batch number: **02K10**
Date of last testing: **20-Apr-2011**

Permanent cell line:
Master cell seed: **SF-21 CB cells**
MCS-batch number: **CCT 9620059T**
Date of last testing: **29-Nov-2006**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF M HYO COMPONENT:

Production step	Start	End	Volume
Batch 55515			
Seed:	12-Sep-2014	12-Sep-2014	60 ml
Harvest:	22-Sep-2014	22-Sep-2014	2000 l
Inactivation:	22-Sep-2014	23-Sep-2014	2021 l
Batch 55516			
Seed:	19-Sep-2014	19-Sep-2014	60 ml
Harvest:	29-Sep-2014	29-Sep-2014	2000 l
Inactivation:	29-Sep-2014	30-Sep-2014	2021 l

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

PRODUCTION OF M HYO COMPONENT:

Production step	Start	End	Volume
Batch 55517			
Seed:	26-Sep-2014	26-Sep-2014	60 ml
Harvest:	06-Oct-2014	06-Oct-2014	2000 l
Inactivation:	06-Oct-2014	07-Oct-2014	2021 l
Batch 55519#			
Seed:	10-Oct-2014	10-Oct-2014	60 ml
Harvest:	20-Oct-2014	20-Oct-2014	2000 l
Inactivation:	20-Oct-2014	21-Oct-2014	2021 l

PRODUCTION OF PCV COMPONENT:

Production step	Start	End	Volume
Batch BPCVM110			
Seed:	15-Sep-2014	15-Sep-2014	57 ml
Harvest:	22-Sep-2014	22-Sep-2014	1878 l
Sonification:	22-Sep-2014	22-Sep-2014	1881 l
Inactivation:	22-Sep-2014	25-Sep-2014	2056 l
Batch BPCVM112			
Seed:	06-Oct-2014	06-Oct-2014	57 ml
Harvest:	13-Oct-2014	13-Oct-2014	1889 l
Sonification:	13-Oct-2014	13-Oct-2014	1887 l
Inactivation:	13-Oct-2014	16-Oct-2014	2067 l

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number:	**C159**
Start date:	**14-Jan-2015**
End date:	**16-Jan-2015**
Total volume:	**4962.0 kg**

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units
M hyo antigen	55515 55516 55517 55519#	661.4 kg
PCV2 antigen	BPCVM110 BPCVM112	880.4 kg
Excipients	214614 214532 214554 C118 C147	2014.6 kg
Alhydrogel 3%	C150	504.6 kg
Adjuvant	C149	901.0 kg

FILLING

Batch number of final bulk:	**C159**
Final batch number:	**C159A**
Start date:	**19-Jan-2015**
End date:	**19-Jan-2015**
Filled containers:	**18 343**
Volume filled:	**100 ml**

IN PROCESS CONTROLS

In process controls M hyo antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch 55515					
Mycoplasma ATP test	22-Sep-2014	22-Sep-2014	55164 RLU	≤ 211196 RLU	Passed
Purity of inoculum	12-Sep-2014	24-Sep-2014	No growth	No growth	Passed
Purity of harvest	22-Sep-2014	24-Sep-2014	No growth	No growth	Passed
Identity	22-Sep-2014	22-Sep-2014	Conform	Conform	Passed
Excess sodiumthiosulfate	10-Oct-2014	10-Oct-2014	Detectable	Detectable	Passed
Inactivation	29-Sep-2014	21-Oct-2014	Inactivated	Inactivated	Passed
Antigen content	30-Oct-2014	30-Oct-2014	27 RPU/ml	≥ 15 RPU/ml	Passed
Sterility	30-Sep-2014	14-Oct-2014	No growth	No growth	Passed

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

In process controls M hyo antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch 55516					
Mycoplasma ATP test	29-Sep-2014	29-Sep-2014	7816 RLU	≤ 211196 RLU	Passed
Purity of inoculum	19-Sep-2014	21-Sep-2014	No growth	No growth	Passed
Purity of harvest	29-Sep-2014	01-Oct-2014	No growth	No growth	Passed
Identity	29-Sep-2014	29-Sep-2014	Conform	Conform	Passed
Excess sodiumthiosulfate	10-Oct-2014	10-Oct-2014	Detectable	Detectable	Passed
Inactivation	06-Oct-2014	28-Oct-2014	Inactivated	Inactivated	Passed
Antigen content	06-Nov-2014	06-Nov-2014	30 RPU/ml	≥ 15 RPU/ml	Passed
Sterility	07-Oct-2014	21-Oct-2014	No growth	No growth	Passed
Batch 55517					
Mycoplasma ATP test	06-Oct-2014	06-Oct-2014	52302 RLU	≤ 211196 RLU	Passed
Purity of inoculum	26-Sep-2014	28-Sep-2014	No growth	No growth	Passed
Purity of harvest	06-Oct-2014	08-Oct-2014	No growth	No growth	Passed
Identity	06-Oct-2014	06-Oct-2014	Conform	Conform	Passed
Excess sodiumthiosulfate	10-Oct-2014	10-Oct-2014	Detectable	Detectable	Passed
Inactivation	13-Oct-2014	04-Nov-2014	Inactivated	Inactivated	Passed
Antigen content	06-Nov-2014	06-Nov-2014	37 RPU/ml	≥ 15 RPU/ml	Passed
Sterility	13-Oct-2014	27-Oct-2014	No growth	No growth	Passed
Batch 55519#					
Mycoplasma ATP test	20-Oct-2014	20-Oct-2014	84118 RLU	≤ 211196 RLU	Passed
Purity of inoculum	10-Oct-2014	12-Oct-2014	No growth	No growth	Passed
Purity of harvest	20-Oct-2014	22-Oct-2014	No growth	No growth	Passed
Identity	20-Oct-2014	20-Oct-2014	Conform	Conform	Passed
Excess sodiumthiosulfate	04-Nov-2014	04-Nov-2014	Detectable	Detectable	Passed
Inactivation	27-Oct-2014	18-Nov-2014	Inactivated	Inactivated	Passed
Antigen content	14-Nov-2014	14-Nov-2014	39 RPU/ml	≥ 15 RPU/ml	Passed
Sterility	28-Oct-2014	11-Nov-2014	No growth	No growth	Passed

In process controls PCV2 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BPCVM110					
Number Infected cells	24-Sep-2014	24-Sep-2014	100 %	≥ 80 %	Passed
Titration live virus	02-Oct-2014	07-Oct-2014	7.0 *$TCID_{50}$	≤ 9.9*$TCID_{50}$	Passed
Cell disruption	22-Sep-2014	22-Oct-2014	99 %	≥ 80 %	Passed
Inactivation	09-Oct-2014	23-Oct-2014	Inactivated	Inactivated	Passed
Sodium thiosulphate	10-Oct-2014	10-Oct-2014	48 mM	33 – 120 mM	Passed
Antigen content	01-Oct-2014	01-Oct-2014	14486 AU/ml	≥ 2000 AU/ml	Passed
Sterility	03-Oct-2014	17-Oct-2014	No growth	No growth	Passed

*Log_{10}/ml

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Manufacturer's Batch Protocol

Product: Porcilis PCV M Hyo *Batch:C159A01*

In process controls PCV2 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BPCVM112					
Number Infected cells	13-Oct-2014	13-Oct-2014	99 %	≥ 80 %	Passed
Titration live virus	23-Oct-2014	28-Oct-2014	7.0 *$TCID_{50}$	≤ 9.9*$TCID_{50}$	Passed
Cell disruption	27-Oct-2014	27-Oct-2014	95 %	≥ 80 %	Passed
Inactivation	06-Nov-2014	20-Nov-2014	Inactivated	Inactivated	Passed
Sodium thiosulphate	30-Oct-2014	30-Oct-2014	48 mM	33 – 120 mM	Passed
Antigen content	12-Nov-2014	12-Nov-2014	13670 AU/ml	≥ 2000 AU/ml	Passed
Sterility	29-Oct-2014	12-Nov-2014	No growth	No growth	Passed

*Log_{10}/ml

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	19-Jan-2015	19-Jan-2015	102 g	> 101 g.	Passed