MSD
Animal Health

Intervet International bv
P.O. Box 31
5830 AA Boxmeer
The Netherlands
T +31 485 58 7600
F +31 485 56 8111
msd-animal-health.com

Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A108A02*

MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

Antigen containing component:

Trade name:	**Bovilis BVD**
Marketing authorisation number:	
Target species:	**Cattle**
Total number of containers in this batch:	**11 036**
Number of containers the release is applied for:	**11 036**
Number of doses per container:	**50**
Number of samples for the competent authority:	-
Date of expiry:	**Feb-2016**
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**

02-Dec-2014/as
1103499663/10

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Bovine viral diarrhoea vaccine (inactivated).**
Batch number of finished product:	**A108A02**
Batch number of final bulk:	**A108**
Pharmaceutical form of finished product:	**Suspension for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**21-Aug-2014**
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: P.G. Mooren
Function: Qualified Person
Date: 09 DEC 2014
Signature:

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FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (F09)
18-Aug-2014	08-Sep-2014	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed
03-Oct-2014	15-Oct-2014	**Inactivation (F03)** Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using mice (F11)
21-Aug-2014	09-Oct-2014	Result: Conform Threshold: Conform Conclusion: Passed
		Potency BVDV (VN)
		Single result: 7 / 9 / 7 / 9 / 9 / 10 Log 2 Average: 8.5 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed
		Methyl parahydroxybenzoate (F08)
20-Oct-2014	20-Oct-2014	Result: 1.5 mg/mL Threshold: 1.2 - 1.8 mg/mL Conclusion: Passed
		Aluminium (F08)
02-Sep-2014	02-Sep-2014	Tested according to Ph. Eur. 2.5.13 Result: 3.6 mg/mL Threshold: 3.0 - 4.5 mg/mL Conclusion: Passed
		pH (F08)
19-Sep-2014	19-Sep-2014	Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 - 7.8 Conclusion: Passed

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Product: Bovilis BVD *Batch: A108A02*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Visual appearance (F08)
14-Aug-2014	14-Aug-2014	Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
		Final inspection (F13)
14-Aug-2014	14-Aug-2014	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

Trade register No: 16028015

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A108A02*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
Antigen	See composition table	Intervet, Boxmeer, the Netherlands
Bulk vaccin	see blending	Intervet, Boxmeer, the Netherlands
Filled product	see filling	Intervet, Boxmeer, the Netherlands

STARTING MATERIALS:

Virus seed lots:
Master seed material: **BVD virus strain C86**
MS-batch number: **F22.4.91**
Date of last testing: **25-AUG-1994**

Working seed material: **BVD virus strain C86**
WS-batch number: **27D09**
Date of last testing: **10-Jul-2009**

Permanent cell line:
Master cell seed: **JCK cell line**
MCS-batch number: **JCK 56° MCS/3**
Date of last testing: **11-MAY-1999**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF BVD COMPONENT:

Production step	Start	End	Volume
Batch BBVD3110			
Seed:	26-Nov-2013	26-Nov-2013	0.0157 ml/rb
Harvest:	02-Dec-2013	02-Dec-2013	481.0 kg
Inactivation:	02-Dec-2013	02-Dec-2013	503.5 kg
Batch BBVD3111			
Seed:	29-Nov-2013	29-Nov-2013	0.0178 ml/rb
Harvest:	05-Dec-2013	05-Dec-2013	596.0 kg
Inactivation:	05-Dec-2013	05-Dec-2013	619.0 kg

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Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A108A02*

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A108**
Start date: **06-Aug-2014**
End date: **08-Aug-2014**
Total volume: **1163.8 kg**

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BBVD3110 BBVD3111	58.90 kg	5.06 %
Adjuvant	0000269573 0000301776 0000304114	580.30 kg	49.86 %
Excipient	0000292226 0000275655 BMGM410691 0000302147	522.81 kg	44.92 %
Preservative	0000293273	1.74 kg	0.15 %

FILLING

Batch number of final bulk: **A108**
Final batch number: **A108A**
Start date: **12-Aug-2014**
End date: **12-Aug-2014**
Filled containers: **11 036**
Volume filled: **100 ml**

IN PROCESS CONTROLS

In process controls BVD antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BBVD3110					
Antigen content	31-Dec-2013	31-Dec-2013	457 EU/ml	n.a.	Passed
Inactivation	06-Dec-2013	18-Dec-2013	Inactivated	Inactivated	Passed
Sterility	16-Dec-2013	06-Jan-2014	No growth	No growth	Passed

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In process controls BVD antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BBVD3111					
Antigen content	09-Jan-2014	09-Jan-2014	510 EU/ml	n.a.	Passed
Inactivation	06-Dec-2013	18-Dec-2013	Inactivated	Inactivated	Passed
Sterility	19-Dec-2013	09-Jan-2014	No growth	No growth	Passed

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	12-Aug-2014	12-Aug-2014	103 ml	>= 102 ml	Passed