

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch:A110A01

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: **27 935**

Number of containers the release
is applied for: **27 935**

Number of doses per container: **10**

Number of samples for the
competent authority: **-**

Date of expiry: **Apr-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**

27-Feb-2015/RD

1103595121/10

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Batch: *A110A01*

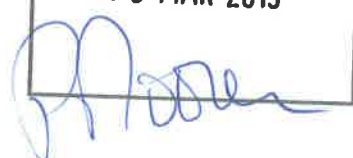
SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	Bovine viral diarrhoea vaccine (inactivated).
Batch number of finished product:	A110A01
Batch number of final bulk:	A110
Pharmaceutical form of finished product:	Suspension for injection
Type of final container:	PET bottles
Date of start of period of validity:	30-Oct-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:
Function:
Date:
Signature:

P.G. Mooren
Qualified Person
05 MAR 2015


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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
29-Oct-2014	19-Nov-2014	<u>Sterility (F09)</u> Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed
21-Nov-2014	03-Dec-2014	<u>Inactivation (F03)</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed
30-Oct-2014	18-Dec-2014	<u>Potency using mice (F11)</u> Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency BVDV (VN)</u> Single result: 12 / 11 / 11 / 12 / 10 / 8 Log 2 Average: 10.7 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed
11-Nov-2014	11-Nov-2014	<u>Methyl parahydroxybenzoate (F08)</u> Result: 1.5 mg/mL Threshold: 1.2 – 1.8 mg/mL Conclusion: Passed
23-Dec-2014	23-Dec-2014	<u>Aluminium (F08)</u> Tested according to Ph. Eur. 2.5.13 Result: 3.8 mg/mL Threshold: 3.0 – 4.5 mg/mL Conclusion: Passed
14-Nov-2014	14-Nov-2014	<u>pH (F08)</u> Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 – 7.8 Conclusion: Passed

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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
22-Oct-2014	22-Oct-2014	<u>Visual appearance (F08)</u> Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
22-Oct-2014	22-Oct-2014	<u>Final inspection (F13)</u> Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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PRODUCTION INFORMATION

<u>Component</u>	<u>Batch</u>	<u>Site(s) of manufacturing</u>
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:

<u>Production step</u>	<u>Start</u>	<u>End</u>	<u>Volume</u>
Batch BBVD3113			
Seed:	06-Dec-2013	06-Dec-2013	0.0197 ml/rb
Harvest:	12-Dec-2013	12-Dec-2013	702 kg
Inactivation:	12-Dec-2013	12-Dec-2013	728 kg
Batch BBVD3114			
Seed:	10-Dec-2013	10-Dec-2013	0.0192 ml/rb
Harvest:	16-Dec-2013	16-Dec-2013	486 kg
Inactivation:	16-Dec-2013	16-Dec-2013	504.5 kg
Batch BBVD3115			
Seed:	13-Dec-2013	13-Dec-2013	0.02 ml/rb
Harvest:	19-Dec-2013	19-Dec-2013	698 kg
Inactivation:	19-Dec-2013	19-Dec-2013	717 kg

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CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A110**
Start date: **08-Oct-2014**
End date: **09-Oct-2014**
Total volume: **1246.6 kg**

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BBVD3113	63.20 kg	5.06 %
	BBVD3114		
	BBVD3115		
Adjuvant	0000301776	627.10 kg	50.30 %
	0000304114		
Excipient	0000292226	554.45 kg	44.48 %
	0000275655		
	BMGM414221		
	0000302147		
Preservative	0000293273	1.88 kg	0.15 %

FILLING

Batch number of final bulk: **A110**
Final batch number: **A110A**
Start date: **17-Oct-2014**
End date: **17-Oct-2014**
Filled containers: **27 935**
Volume filled: **20 ml**

IN PROCESS CONTROLS

In process controls BVD antigen:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Batch BBVD3113					
Antigen content	09-Jan-2014	09-Jan-2014	575 EU/ml	≥ 250 EU/ml	Passed
Inactivation	13-Dec-2013	25-Dec-2013	Inactivated	Inactivated	Passed
Sterility	02-Jan-2014	23-Jan-2014	No growth	No growth	Passed

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In process controls BVD antigen:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Batch BBVD3114					
Antigen content	09-Jan-2014	09-Jan-2014	431 EU/ml	≥ 250 EU/ml	Passed
Inactivation	24-Dec-2013	15-Jan-2014	Inactivated	Inactivated	Passed
Sterility	10-Jan-2014	31-Jan-2014	No growth	No growth	Passed
Batch BBVD3115					
Antigen content	09-Jan-2014	09-Jan-2014	542 EU/ml	≥ 250 EU/ml	Passed
Inactivation	03-Jan-2014	15-Jan-2014	Inactivated	Inactivated	Passed
Sterility	15-Jan-2014	05-Feb-2014	No growth	No growth	Passed

In process controls final product:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Filling volume	17-Oct-2014	17-Oct-2014	21 ml	≥ 21 ml	Passed