

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A099A01

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: **30 252**

Number of containers the release
is applied for: **30 252**

Number of doses per container: **10**

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

Date of expiry: **Ju1-2015**

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**

21-May-2014/s1

1103229998/10



MSD
Animal Health

Intervet International bv
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msd-animal-health.com

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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:	A099A01
Batch number of final bulk:	A099
Pharmaceutical form of finished product:	Suspension for injection
Type of final container:	PET bottles
Date of start of period of validity:	30-Jan-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
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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:

S.T.M. Verstegen Qualified Person 03 JUN 2014 

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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
05-Feb-2014	26-Feb-2014	<p><u>Sterility (F09)</u> Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed</p>
07-Feb-2014	19-Feb-2014	<p><u>Inactivation (F03)</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed</p>
30-Jan-2014	20-Mar-2014	<p><u>Potency using mice (F11)</u> Result: Conform Threshold: Conform Conclusion: Passed</p> <p><u>Potency BVDV (VN)</u> Single result: 8 / 8 / 10 / 5 / 7 / 7 Log 2 Average: 7.5 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed</p>
02-Apr-2014	02-Apr-2014	<p><u>Methyl parahydroxybenzoate (F08)</u> Result: 1.4 mg/mL Threshold: 1.2 – 1.8 mg/mL Conclusion: Passed</p>
10-Feb-2014	10-Feb-2014	<p><u>Aluminium (F08)</u> Tested according to Ph. Eur. 2.5.13 Result: 3.7 mg/mL Threshold: 3.0 – 4.5 mg/mL Conclusion: Passed</p>
28-Feb-2014	28-Feb-2014	<p><u>pH (F08)</u> Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 – 7.8 Conclusion: Passed</p>



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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
23-Jan-2014	23-Jan-2014	<u>Visual appearance (F08)</u> Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
23-Jan-2014	23-Jan-2014	<u>Final inspection (F13)</u> Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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Manufacturer's Batch Protocol

*Product: Bovilis BVD**Batch: A099A01*

PRODUCTION INFORMATION

<u>Component</u>	<u>Batch</u>	<u>Site(s) of manufacturing</u>
Antigen	See composition table	Intervet, Boxmeer, the Netherlands
Antigen	See composition table	Intervet, Salamanca, Spain
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 BBVD3101			
Seed:	31-May-2013	31-May-2013	0.0142 ml/rb
Harvest:	06-Jun-2013	06-Jun-2013	470 kg
Inactivation:	06-Jun-2013	06-Jun-2013	499 kg
Batch SBVD13001			
Seed:	28-May-2013	28-May-2013	0.03 ml/rb
Harvest:	03-Jun-2013	03-Jun-2013	690.40 kg
Inactivation:	03-Jun-2013	03-Jun-2013	704.50 kg

CREATION OF THE FINISHED PRODUCT

BLENDED OF FINAL BULK:

Batch number: **A099**
 Start date: **15-Jan-2014**
 End date: **16-Jan-2014**
 Total volume: **904.9 kg**

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COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	SBVD13001 BBVD3101	38.90 kg	4.30 %
Adjuvant	0000269573 0000284049 0000269574	454.30 kg	50.20 %
Excipient	0000257120 0000219280 BMGM318601 BMGM312071 0000264744	410.37 kg	45.35 %
Preservative	0000198409	1.36 kg	0.15 %

FILLING

Batch number of final bulk: **A099**
 Final batch number: **A099A**
 Start date: **20-Jan-2014**
 End date: **20-Jan-2014**
 Filled containers: **30 252**
 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 BBVD3101					
Antigen content	30-Jul-2013	30-Jul-2013	500 EU/ml	n.a.	Passed
Inactivation	09-Aug-2013	21-Aug-2013	Inactivated	Inactivated	Passed
Sterility	14-Jun-2013	05-Jul-2013	No growth	No growth	Passed

Batch SBVD13001

Antigen content	30-Jul-2013	30-Jul-2013	770 EU/ml	n.a.	Passed
Inactivation	07-Jun-2013	19-Jun-2013	Inactivated	Inactivated	Passed
Sterility	07-Jun-2013	28-Jun-2013	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	20-Jan-2014	20-Jan-2014	21 ml	>= 21 ml	Passed