

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A102A01

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:

11 693

Number of containers the release
is applied for:

11 693

Number of doses per container:

50

Number of samples for the
competent authority:

-

Date of expiry:

Sep-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**

19-Jun-2014/mw

1103249641/10

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Batch: A102A01

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	Bovine viral diarrhoea vaccine (inactivated).
Batch number of finished product:	A102A01
Batch number of final bulk:	A102
Pharmaceutical form of finished product:	Suspension for injection
Type of final container:	PET bottles
Date of start of period of validity:	10-Mar-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>P.G. Mooren Qualified Person</p> <p>25 JUN 2014</p> 
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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
10-Mar-2014	31-Mar-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>
02-Apr-2014	14-Apr-2014	<p><u>Inactivation (F03)</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed</p>
10-Mar-2014	28-Apr-2014	<p><u>Potency using mice (F11)</u> Result: Conform Threshold: Conform Conclusion: Passed</p> <p><u>Potency BVDV (VN)</u> Single result: 9 / 9 / 11 / 8 / 10 / 9 Log 2 Average: 9.3 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed</p>
02-Apr-2014	02-Apr-2014	<p><u>Methyl parahydroxybenzoate (F08)</u> Result: 1.5 mg/mL Threshold: 1.2 – 1.8 mg/mL Conclusion: Passed</p>
15-Apr-2014	15-Apr-2014	<p><u>Aluminium (F08)</u> Tested according to Ph. Eur. 2.5.13 Result: 3.6 mg/mL Threshold: 3.0 – 4.5 mg/mL Conclusion: Passed</p>
14-Mar-2014	14-Mar-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>
04-Mar-2014	04-Mar-2014	<u>Visual appearance (F08)</u> Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
04-Mar-2014	04-Mar-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, 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 SBVD13007			
Seed:	18-Oct-2013	18-Oct-2013	0.03 ml/rb
Harvest:	24-Oct-2013	24-Oct-2013	697.00 kg
Inactivation:	24-Oct-2013	24-Oct-2013	711.20 kg
Batch SBVD13008			
Seed:	25-Oct-2013	25-Oct-2013	0.03 ml/rb
Harvest:	31-Oct-2013	31-Oct-2013	693.00 kg
Inactivation:	31-Oct-2013	31-Oct-2013	707.10 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A102**
Start date: **19-Feb-2014**
End date: **20-Feb-2014**
Total volume: **1250.3 kg**

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COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	SBVD13007 SBVD13008	45.40 kg	3.63 %
Adjuvant	0000284049 0000269574 0000284050	622.50 kg	49.79 %
Excipient	0000257120 0000275655 BMGM321281 BMGM400601 0000275652	580.54 kg	46.43 %
Preservative	0000198409	1.88 kg	0.15 %

FILLING

Batch number of final bulk: **A102**
Final batch number: **A102A**
Start date: **25-Feb-2014**
End date: **26-Feb-2014**
Filled containers: **11 693**
Volume filled: **100 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 SBVD13007					
Antigen content	28-Nov-2013	28-Nov-2013	666 EU/ml	n.a.	Passed
Inactivation	01-Nov-2013	13-Nov-2013	Inactivated	Inactivated	Passed
Sterility	30-Oct-2013	20-Nov-2013	No growth	No growth	Passed
Batch SBVD13008					
Antigen content	28-Nov-2013	28-Nov-2013	712 EU/ml	n.a.	Passed
Inactivation	08-Nov-2013	20-Nov-2013	Inactivated	Inactivated	Passed
Sterility	06-Nov-2013	27-Nov-2013	No growth	No growth	Passed

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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	25-Feb-2014	26-Feb-2014	103 ml	>= 102 ml	Passed