

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A107B02

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:	56 406
Number of containers the release is applied for:	56 406
Number of doses per container:	10
Number of samples for the competent authority:	-
Date of expiry:	Jan-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

08-Jan-2015/cc
1103544087/10

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A107B02

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	Bovine viral diarrhoea vaccine (inactivated).
Batch number of finished product:	A107B02
Batch number of final bulk:	A107
Pharmaceutical form of finished product:	Suspension for injection
Type of final container:	PET bottles
Date of start of period of validity:	01-Jul-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:

<p>P.G. Mooren Qualified Person</p> <p>08 JAN 2015</p> 
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**MSD**

Animal Health

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Manufacturer's Batch Protocol

*Product: Bovilis BVD**Batch: A107B02*

FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
03-Jul-2014	24-Jul-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>
25-Jul-2014	06-Aug-2014	<p><u>Inactivation (F03)</u> Result: Inactivated Threshold: Inactivated Conclusion: Passed</p>
01-Jul-2014	19-Aug-2014	<p><u>Potency using mice (F11)</u> Result: Conform Threshold: Conform Conclusion: Passed</p> <p><u>Potency BVDV (VN)</u> Single result: 12 / 12 / 9 / 10 / 9 Log 2 Average: 10.4 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed</p>
14-Jul-2014	14-Jul-2014	<p><u>Methyl parahydroxybenzoate (F08)</u> Result: 1.5 mg/mL Threshold: 1.2 – 1.8 mg/mL Conclusion: Passed</p>
25-Jul-2014	25-Jul-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>
24-Jul-2014	24-Jul-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>

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A107B02

FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
01-Jul-2014	01-Jul-2014	<u>Visual appearance (F08)</u> Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
01-Jul-2014	01-Jul-2014	<u>Final inspection (F13)</u> Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A107B02

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 BBVD3108			
Seed:	19-Nov-2013	19-Nov-2013	0.0178 ml/rb
Harvest:	25-Nov-2013	25-Nov-2013	485.0 kg
Inactivation:	25-Nov-2013	25-Nov-2013	502.0 kg
Batch BBVD3109			
Seed:	22-Nov-2013	22-Nov-2013	0.0191 ml/rb
Harvest:	28-Nov-2013	28-Nov-2013	706.0 kg
Inactivation:	28-Nov-2013	28-Nov-2013	736.0 kg

CREATION OF THE FINISHED PRODUCT

BLENDED OF FINAL BULK:

Batch number:	A107
Start date:	17-Jun-2014
End date:	18-Jun-2014
Total volume:	1248.8 kg

Manufacturer's Batch Protocol

Product: Bovilis BVD

Batch: A107B02

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BBVD3108 BBVD1309	71.40 kg	5.72 %
Adjuvant	0000269573 0000284050 0000304114	626.30 kg	50.15 %
Excipient	0000292226 0000275655 BMGM406121 0000302147	549.23 kg	43.98 %
Preservative	0000293273	1.88 kg	0.15 %

FILLING

Batch number of final bulk: **A107**
Final batch number: **A107B**
Start date: **25-Jun-2014**
End date: **26-Jun-2014**
Filled containers: **56 406**
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 BBVD3108					
Antigen content	31-Dec-2013	31-Dec-2013	447 EU/ml	n.a.	Passed
Inactivation	29-Nov-2013	11-Dec-2013	Inactivated	Inactivated	Passed
Sterility	16-Dec-2013	06-Jan-2014	No growth	No growth	Passed
Batch BBVD3109					
Antigen content	31-Dec-2013	31-Dec-2013	431 EU/ml	n.a.	Passed
Inactivation	29-Nov-2013	11-Dec-2013	Inactivated	Inactivated	Passed
Sterility	16-Dec-2013	06-Jan-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	25-Jun-2014	26-Jun-2014	21 ml	>= 21 ml	Passed

**MSD**

Animal Health

**Model for manufacturers of a
MARKETING INFORMATION FORM**

Intervet International bv

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Notification of the intention to market a batch of an immunological veterinary medicinal product, which has a marketing authorisation in the following EC/EEA Member State Hungary and has received an EC Batch release certificate after OBPR or OCABR in another Member State in accordance with Article 81 or Article 82 of EC Directive 2004/28/EC and in view of mutual recognition.

Trade name in the above mentioned Member State:	Bovilis BVD
International non-proprietary name / Ph. Eur. name / common name:	Bovine viral diarrhoea vaccine (inactivated).
Name and address of Marketing Authorisation Holder (MAH) for the above mentioned Member State:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Represented by the local company
Market authorisation number in the above mentioned Member State:	2974/1-5/11 MgSzH ÁTI
Identification numbers associated with the lot to be marketed in the above mentioned Member State:	
Bulk number (final formulated bulk):	A107
Final lot number:	A107B
Packaging lot number (if different from final lot n°):	A107B02
Batch number of diluent: (where appropriate)	-
Type of Container:	PET Bottles
Number of doses/volume of container:	10
Total number of containers to be marketed in the above noted Member State:	540
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Jan-2016

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	OBPR
Official batch release certificate number:	20398/14

I hereby declare that:

- this batch is in compliance with the above marketing authorisation and the relevant European Pharmacopoeia monographs;
- this batch is the batch referred to in the accompanying batch release certificate;
- a copy of the batch release certificate (in the case of OCABR with the annexed test results) and the manufacturer's protocol are attached.

Signature of qualified person (MAH):	
Name of qualified person (MAH):	P.G. Mooren Qualified Person
Date of issue:	08 JAN 2015

Use of the following section is optional

For completion by the CA/OMCL after submission:

Date received:	
Signature of qualified authority (CA/OMCL):	
Name of qualified authority (CA/OMCL):	
Decision and Date:	

08-Jan-2015/cc

EDQM ♦ OCABR/OBPR of IVMPs 2010

Paul-Ehrlich-Institut Postfach D-63207 Langen

Intervet Deutschland GmbH
Feldstraße 1a
D - 85716 Unterschleißheim

Reference Number: 20398/14

Administrative Code: 4/3:2.03.01.0094

Date of Release of Certificate: 09.10.2014

**EU/EEA OFFICIAL BATCH PROTOCOL REVIEW
CERTIFICATE OF APPROVAL
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS**

Examined under Article 81 of Directive 2001/82/EC as amended by Directive 2004/28/EC


Trade name:	Bovilis BVD-MD
International non-proprietary name / Ph. Eur. name / common name:	Bovine viral diarrhoea vaccine (inactivated)
Name and address of manufacturer responsible for batch release:	Intervet International B.V. Wim de Körverstraat 35 P.O. Box 31 NL-5830 AA Boxmeer
Marketing authorisation number (Member State / EC):	180a/96
Manufacturer's batch number(s): - final bulk no - final lot no - packaging lot no	A107 A107B A107B01-10
Batch number of diluent (where appropriate):	-
Type of container:	Glass Bottles
Total number of containers of this batch:	56,406
Number of doses/volume per container:	10
Date of start of period of validity:	01.07.2014
Expiry date:	12.2015

This batch has been examined using documented procedures that form part of a quality management system.

The signed manufacturer's release protocol for this batch has been examined in conformity with Article 81.

This batch is in compliance with all of the approved specifications laid down in the above noted marketing authorisation.

Fees are laid down separately.


Dr. Ingun Lemke



Paul-Ehrlich-Institut Postfach 63207 Langen

Intervet Deutschland GmbH
Feldstraße 1a
D-85716 Unterschleißheim

Aktenzeichen: 4/3: 2.03.01.0094
Ihr Zeichen:

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08.12.2014

Bovilis BVD-MD, Zul.-Nr. 180a/96
Änderung des Bescheides über die staatliche Chargenfreigabe
Hier: Änderung des Behältnistyps

Sehr geehrte Damen und Herren,

der Bescheid über die Freigabe der Chargen A107B01-10 des Mittels Bovilis BVD-MD, Zul.-Nr. 180a/96, vom 09.10.2014 (B.-Nr. 20398/14) wird geändert.

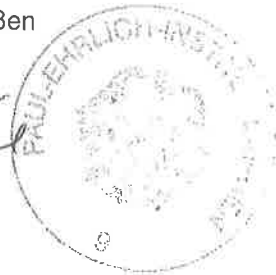
Der Behältnistyp entspricht korrekterweise PET-Flaschen anstatt Glasflaschen.

Begründung:

Nach § 42 Verwaltungsverfahrensgesetz kann das Paul-Ehrlich-Institut Schreibfehler, Rechenfehler und ähnliche offenbare Unrichtigkeiten in einem Verwaltungsakt jederzeit berichtigen. Der o.g. Bescheid zur Chargenfreigabe wird entsprechend geändert.

Mit freundlichen Grüßen
Im Auftrag


Dr. Ingun Lemke



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Feldstraße 1a
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Aktenzeichen: 4/3: 2.03.01.0094
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08.12.2014

Bovilis BVD-MD, Marketing Authorisation Number 180a/96
Amendment of the European Community/EEA Official Batch Protocol Review Certificate of Approval for Immunological Veterinary Products, batch no. A107B01-10
Re: Correction of the type of container

AMENDMENT

Hereby the certificate concerning the release for batches A107B01-10 of the product Bovilis BVD-MD, marketing authorisation number 180a/96, dated 09.10.2014 (ref no. 20398/14), shall be amended as follows:

Type of container	PET bottles
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Justification:

The certificates dated 09.10.2014 are amended according to § 42 VwVfG (German Administrative Procedures Law) as an incorrect type of containers (glass bottles instead of PET bottles) was erroneously given.

By order



Dr. Ingun Lemke

