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

MSD Animal Health

Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A087B01*

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:	**17 143**
Number of containers the release is applied for:	**17 143**
Number of doses per container:	**10**
Number of samples for the competent authority:	**-**
Date of expiry:	**Dec-2014**
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**

17-Dec-2013/ce
1102997440/10

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

MSD Animal Health

Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A087B01*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Bovine viral diarrhoea vaccine (inactivated).**
Batch number of finished product:	**A087B01**
Batch number of final bulk:	**A087**
Pharmaceutical form of finished product:	**Suspension for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**27-Jun-2013**
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: 24 DEC 2013
Signature:

Trade register No: 16028015

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: A087B01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (F09)
24-Jun-2013	15-Jul-2013	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed
28-Jun-2013	10-Jul-2013	**Inactivation (F03)** Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using mice (F11)
27-Jun-2013	15-Aug-2013	Result: Conform Threshold: Conform Conclusion: Passed
		Potency BVDV (VN)
		Single result: 11 / 9 / 8 / 10 / 10 Log 2 Average: 9.8 Log 2 Threshold: >= 5.6 Log 2 Conclusion: Passed
		Methyl parahydroxybenzoate (F08)
25-Jun-2013	25-Jun-2013	Result: 1.5 mg/mL Threshold: 1.2 - 1.8 mg/mL Conclusion: Passed
		Aluminium (F08)
12-Sep-2013	12-Sep-2013	Tested according to Ph. Eur. 2.5.13 Result: 3.7 mg/mL Threshold: 3.0 - 4.5 mg/mL Conclusion: Passed
		pH (F08)
07-Aug-2013	07-Aug-2013	Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 - 7.8 Conclusion: Passed

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

MSD Animal Health

Manufacturer's Batch Protocol

Product: Bovilis BVD *Batch: A087B01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Visual appearance (F08)
20-Jun-2013	20-Jun-2013	Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
		Final inspection (F13)
20-Jun-2013	20-Jun-2013	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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: A087B01*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
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:

Production step	Start	End	Volume
Batch BBVD2106			
Seed:	20-Jan-2012	20-Jan-2012	0.0204 ml/rb
Harvest:	26-Jan-2012	26-Jan-2012	481 kg
Inactivation:	26-Jan-2012	26-Jan-2012	501 kg
Batch SBVD12003			
Seed:	20-Jan-2012	20-Jan-2012	0.03 ml/rb
Harvest:	26-Jan-2012	26-Jan-2012	684 kg
Inactivation:	26-Jan-2012	26-Jan-2012	698 kg

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: A087B01*

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A087**
Start date: **12-Jun-2013**
End date: **13-Jun-2013**
Total volume: **1243.2 kg**

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BBVD2106 SBVD12003	46.40 kg	3.70 %
Adjuvant	0000249962 0000249965	625.00 kg	50.27 %
Excipient	0000238437 0000219280 BMGM307731 BMGM308821 0000236798	569.95 kg	45.85 %
Preservative	0000198409	1.88 kg	0.15 %

FILLING

Batch number of final bulk: **A087**
Final batch number: **A087B**
Start date: **17-Jun-2013**
End date: **17-Jun-2013**
Filled containers: **17 143**
Volume filled: **20 ml**

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: A087B01*

IN PROCESS CONTROLS

In process controls BVD antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BBVD2106					
Antigen content	15-Feb-2012	15-Feb-2012	606 EU/ml	n.a.	Passed
Inactivation	27-Jan-2012	08-Feb-2012	Inactivated	Inactivated	Passed
Sterility	09-Feb-2012	01-Mar-2012	No growth	No growth	Passed
Batch SBVD12003					
Antigen content	15-Feb-2012	15-Feb-2012	808 EU/ml	n.a.	Passed
Inactivation	03-Feb-2012	15-Feb-2012	Inactivated	Inactivated	Passed
Sterility	01-Feb-2012	22-Feb-2012	No growth	No growth	Passed

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	17-Jun-2013	17-Jun-2013	21 ml	>= 21 ml	Passed

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

MSD Animal Health

Model for manufacturers of a MARKETING INFORMATION FORM

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 Directive2004/28/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):	**A087**
Final lot number:	**A087B**
Packaging lot number (if different from final lot n°):	**A087B01**
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:	Dec-2014

CA/OMCL performing batch release:	VMD
Type of certificate: (i.e.: OCABR or OBPR)	OBPR
Official batch release certificate number:	13/B1620

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):	P.G. Mooren Qualified Person
Name of qualified person (MAH):	
Date of issue:	24 DEC 2013

---------- 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:	

24-Dec-2013/sl

EUROPEAN COMMUNITY/EEA OFFICIAL BATCH PROTOCOL REVIEW CERTIFICATE OF APPROVAL FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Name and address of the control authority performing the document review: Veterinary Medicines Directorate. Woodham Lane, New Haw, Surrey. KT15 3LS

Examined under Article 81of Directive 2001/82/EC as amended by Directive 2004/28/EC in accordance with the current Procedure for harmonised application of Article 81 for Official Batch Protocol Review of immunological veterinary medicinal products in the European Community.

Trade name:	**Bovilis BVD Suspension for Injection for Cattle**
International non-proprietary **Name / Ph. Eur.** name / common name	
Name and address of marketing authorisation holder	Intervet International BV, Wim De Korverstraat 35, PO Box 31, Boxmeer, 5830 AA, The Netherlands
Name and address of manufacturer, if different:	Intervet International BV, PO Box 31, 5830 AA Boxmeer, , Netherlands
Marketing authorisation number (Member State / EC) issued by	06376/4025
Manufacturer's batch number(s) appearing on package and other identification numbers associated with this batch (final bulk no, final lot no, packaging lot no)	A087B
Batch number of diluent (where appropriate)	
Type of container:	PET Bottles
Total number of containers in this batch[2]:	17143
Number of doses/volume per container:	10 / 20ml
Date of start of period of validity: Shelf life: Expiry date:	27/06/13 18 M 30/11/14

The signed manufacturer's release protocol for this batch has been examined in conformity with the current procedure for harmonised application of Article 81 for OBPR in the European Community.

This batch **IS in compliance** with all of the approved specification laid down in the above noted marketing authorisation.

Certificate Number: 13/B1620

Signed:	T. NASH
Name and function of signatory:	**Tom Nash** Manager of UK Batch Release Arrangements
Date of issue:	27/11/13

[1] Provision of different batch numbers of authorised diluent to different Member States should not impair mutual recognition of OPBR for the batch of active component covered by the certificate, however if a diluent batch different from that on the certificate is provided, protocol documentation on the new diluent batch may be requested in addition to the certificate.

[2] If different fillings exist, please indicate.