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 IBR marker live *Batch: A042AE101*

MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

Antigen containing component:

Trade name:	**Bovilis IBR marker live**
Marketing authorisation number:	
Target species:	**Cattle**
Total number of containers in this batch:	**72 477**
Number of containers the release is applied for:	**72 477**
Number of doses per container:	**50**
Number of samples for the competent authority:	-
Date of expiry:	**Jul-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-Aug-2013/mw
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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A042AE101*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Antigen containing component:

Common name of product:	**Infectious bovine rhinotracheitis vaccine (live).**
Batch number of finished product:	**A042AE101**
Batch number of final bulk:	**A042***
Pharmaceutical form of finished product:	**Lyophilisate + solvent for a suspension for injection/ intranasal application**
Type of final container:	**Hydrolytical class type I glass**
Date of start of period of validity:	**30-Jul-2012**
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.

*Bulk batch number A042 material number 007375, containing CD stabilizer

Name: P.G. Mooren
Function: Qualified Person
Date: 20 AUG 2013
Signature:

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A042AE101*

FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

Date on	Date off	Test results
		Sterility (FPC-01)
17-Jul-2012	31-Jul-2012	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		Mycoplasmas (FPC-02)
02-Dec-2011	30-Dec-2011	Tested according to Ph. Eur. 2.6.7 Result: No mycoplasma detected Threshold: No mycoplasma detected Conclusion: Passed
		Titration BHV-1(TCID50)(FPC-05)
30-Jul-2012	03-Aug-2012	Tested according to Ph. Eur. 0696 Result: 7.9 / 8.0 / 8.0 log 10/VL Average: 8.0 log 10/VL Threshold: 5.7 – 7.3 log 10/dose Conclusion: Passed
		Marker aspect (FPC-07)
17-Jul-2012	14-Aug-2012	Result: No IBR GE- specific antibodies detected Threshold: No IBR GE- specific antibodies detected Conclusion: Passed
		Extraneous agents (in vitro) (FPC-04)
20-Dec-2011	05-Jan-2012	Tested according to Ph. Eur. 0696 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		Identification (FPC-06)
03-Aug-2012	03-Aug-2012	Result: Identity conform Threshold:Identity conform Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A042AE101*

FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

Date on	Date off	Test results
		Residual moisture (FPC-08)
16-Jul-2012	16-Jul-2012	Tested according to Ph. Eur. 2.5.32 Result: 1.5 % Threshold: 0.4 – 4.0 % Conclusion: Passed
		Vacuum (FPC-09)
09-Jul-2012	09-Jul-2012	Result: Conform Threshold: All vials must pass the vacuum test Conclusion: Passed
		Capcode (FPC-09)
09-Jul-2012	09-Jul-2012	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A042AE101*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
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: **gE⁻ BHV-1 virus strain Gk/D**
MS-batch number: **211196**
Last testing: **16-OCT-1997**

Working seed material: **gE⁻ BHV-1 virus strain Gk/D**
WS-batch number: **99.20.002N**
Last testing: **28-Mar-2003**

Permanent cell line:
Master cell seed: **JCK cell line**
MCS-batch number: **56° MCS/3**
Last testing: **11-MAY-1999**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF IBR COMPONENT:

Production step	Start	End	Volume
Batch A042			
Seed:	03-Nov-2011	03-Nov-2011	0.0116 ml/RCB
Harvest:	07-Nov-2011	07-Nov-2011	377.5 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A042A ***
Start date: **07-Nov-2011**
End date: **07-Nov-2011**
Total volume: **515.9 kg**

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A042AE101*

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total Kg	Final Concentration (w/w)
IBR antigen	A042	377.5 Kg	73 %
CD Stabilizer	BMGM117861 BMGM115731	138.4 Kg	27 %

* Bulk batch number A042, material number 007375, containing CD stabilizer

FILLING

Batch number of final bulk:	**A042A**
Final batch number:	**A042A**
Start date:	**04-Jul-2012**
End date:	**04-Jul-2012**
Filled containers:	**72477**
Volume filled:	**2 ml**

LYOPHILISATION:

Final batch number:	**A042A**
Start date:	**04-Jul-2012**
End date:	**06-Jul-2012**
Number of containers:	**72477**

IN PROCESS CONTROLS (antigen containing component)

In process controls IBR Antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch A042 Sterility	01-Dec-2011	15-Dec-2011	No growth	No growth	Passed

In process controls Final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	04-Jul-2012	04-Jul-2012	2.0 ml	1.8-2.2 ml	Passed
Freeze drying	04-Jul-2012	06-Jul-2012	Within spec.	Within spec.	Passed

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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 IBR marker live
International non-proprietary name / Ph. Eur. name / common name:	Infectious bovine rhinotracheitis vaccine (live)
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:	2156/1-7/07 MgSzH ÁTI
Identification numbers associated with the lot to be marketed in the above mentioned Member State;	
Bulk number (final formulated bulk):	**A042**
Final lot number:	**A042A**
Packaging lot number (if different from final lot n°):	**A042AE101**
Batch number of diluent: (where appropriate)	-
Type of Container:	Hydrolytical class type I glass
Number of doses/volume of container:	50
Total number of containers to be marketed in the above noted Member State:	2700
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Jul-2015

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	OCABR
Official batch release certificate number:	1030/13

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:	21 AUG 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:	

20-Aug-2013/as

Trade register No: 16028015

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Postfach D-63207 Langen

Intervet Deutschland GmbH
Feldstraße 1a
D - 85716 Unterschleißheim

Reference Number: 1030/13
Administrative Code: 4/3:2.02.01/2603385
Date of Release of Certificate: 25.03.2013

EUROPEAN COMMUNITY/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

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

Trade name:	Bovilis IBR Marker live
International non-proprietary Name / Ph. Eur. name / common name:	Infectious bovine rhinotracheitis vaccine (live)
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)	PEI.V.11616.01.1
Manufacturer`s batch number(s): - final bulk no - final lot no - packaging lot no	 A042 A042A A042AE101-10
Batch number of diluent (where appropriate):	-
Type of container:	glass vials
Total number of containers of this batch:	72,477
Number of doses/volume per container:	50
Date of start of period of validity:	30.07.2012
Expiry date:	07.2014

DAkkS Deutsche Akkreditierungsstelle D-PL-13072-01-00

This batch has partly been examined using testing procedures for which the Paul-Ehrlich-Institut has been accredited. The accredited testing procedures are shown on http://www.pei.de/qm-en.

This batch has been examined in conformity with Article 82.The examination is based on review of the manufacturer's protocol and repetition of the appropriate control laboratory tests.

This batch is in compliance with the approved specifications laid down in the above-mentioned marketing authorisation.

Technical details for these compliance results are attached to this form.

Fees are laid down separately.

Dr. Ingun Lemke

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Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

AUTHORITY'S TEST REPORT

Trade name:	Bovilis IBR Marker live
Marketing authorisation number:	PEI.V.11616.01.1
Manufacturer's batch number(s): -final bulk no -final lot no -packaging lot no	 A042 A042A A042AE101-10
Expiry date:	07.2014

Results:

Method (SOP):	Appearance (S-31)
Test dates:	20.03.2013
Results:	Conform to specifications.
Specifications:	Pellet must be even. Colour must be without differences.

Results:

Method (SOP):	- Potency test (4/3-S-016) - Test for extraneous pestiviruses (BVDV-PCR)
Test dates:	20.03. - 25.03.2013 / 22.03.2013
Results:	- Virus content 6.0 log10 TCID50/dose. - BVDV-PCR negative.
Specifications	- Virus content 5.7 - 7.3 log10 TCID50/dose. - No specifications for a BVDV-PCR.

Remarks/further tests:

D. Lemke

Dr. Ingun Lemke