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 IBR marker live *Batch: A044CE01*

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:	**73 585**
Number of containers the release is applied for:	**73 585**
Number of doses per container:	**50**
Number of samples for the competent authority:	-
Date of expiry:	**May-2017**
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**

24-Mar-2015/mw
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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A044CE01*

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:	**A044CE01**
Batch number of final bulk:	**A044 ***
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:	**02-May-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.

*Bulk batch number A044, material number 007375, containing CD stabilizer

Name:
Function:
Date:
Signature:

P.G. Mooren
Qualified Person
26 MAR 2015

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A044CE01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

Date on	Date off	Test results
		Sterility (FPC-01)
02-May-2014	16-May-2014	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		Mycoplasmas (FPC-02)
03-Apr-2012	01-May-2012	Tested according to Ph. Eur. 2.6.7 Result: No mycoplasma detected Threshold: No mycoplasma detected Conclusion: Passed
		Titration BHV-1(TCID50)(FPC-05)
02-May-2014	06-May-2014	Tested according to Ph. Eur. 0696 Result: 8.3 / 8.2 / 8.3 log 10/VL Average: 8.3 log 10/VL Threshold: 5.7 - 7.3 log 10/dose Conclusion: Passed
		Marker aspect (FPC-07)
05-Nov-2013	03-Dec-2013	Result: No IBR GE- specific antibodies detected Threshold: No IBR GE- specific antibodies detected Conclusion: Passed
		Extraneous agents (in vitro) (FPC-04)
24-Jul-2012	09-Aug-2012	Tested according to Ph. Eur. 0696 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		Identification (FPC-06)
18-Oct-2013	18-Oct-2013	Result: Identity conform Threshold:Identity conform Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A044CE01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

Date on	Date off	Test results
		Residual moisture (FPC-08)
09-May-2014	09-May-2014	Tested a ccording to Ph. Eur. 2.5.32 Result: 1.8 % Threshold: 0.4 – 4.0 % Conclusion: Passed
		Vacuum (FPC-09)
02-May-2014	05-May-2014	Result: Conform Threshold: All vials must pass the vacuum test Conclusion: Passed
		Capcode (FPC-09)
30-Apr-2014	30-Apr-2014	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A044CE01*

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 A044			
Seed:	22-Mar-2012	22-Mar-2012	0.0119 ml/RCB
Harvest:	26-Mar-2012	26-Mar-2012	373.5 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A044***
Start date: **26-Mar-2012**
End date: **26-Mar-2012**
Total volume: **510.5 kg**

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Manufacturer's Batch Protocol

Product: Bovilis IBR marker live *Batch: A044CE01*

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total Kg	Final Concentration (w/w)
IBR antigen	A044	373.5 Kg	73 %
CD Stabilizer	BMGM117862 BMGM203301	137 Kg	27 %

* Bulk batch number A044, material number 007375, containing CD stabilizer

FILLING

Batch number of final bulk: **A044**
Final batch number: **A044C**
Start date: **22-Apr-2014**
End date: **22-Apr-2014**
Filled containers: **73 585**
Volume filled: **2 ml**

LYOPHILISATION:

Final batch number: **A044C**
Start date: **22-Apr-2014**
End date: **24-Apr-2014**
Number of containers: **73 585**

IN PROCESS CONTROLS (antigen containing component)

In process controls IBR Antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch A044					
Sterility	04-Apr-2012	18-Apr-2012	No growth	No growth	Passed

In process controls Final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	22-Apr-2014	22-Apr-2014	2.0 ml	1.8-2.2 ml	Passed
Freeze drying	22-Apr-2014	24-Apr-2014	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):	**A044**
Final lot number:	**A044C**
Packaging lot number (if different from final lot n°):	**A044CE01**
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:	2 990
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	May-2017

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	Art. 82 (OCABR)
Official batch release certificate number:	20231/15

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.

P.G. Mooren
Qualified Person
26 MAR 2015

Signature of qualified person (MAH):	
Name of qualified person (MAH):	
Date of issue:	

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:	

26-Mar-2015/mw

EDQM ♦ OCABR/OBPR of IVMPS 2010

1025912

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

Administrative Code: 4/3:2.03.01.0093
Reference Number: 20231/15
Date of Release of Certificate: 24.02.2015

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

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	 A044 A044C A044CE01-10
Batch number of diluent (where appropriate):	-
Type of container:	glass vials
Total number of containers of this batch:	73,585
Number of doses/volume per container:	50
Date of start of period of validity:	02.05.2014
Expiry date:	10.2015

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

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.

PAUL-EHRLICH-INSTITUT LANGEN

Dr. Ingun Lemke

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	 A044 A044C A044CE01-10
Expiry date:	10.2015

Results:

Method (SOP):	Appearance (S-31)
Test dates:	20.01.2015
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:	11.02. - 16.02.2015 / 11.02.2015
Results:	- Virus content 7.0 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:

The test for extraneous pestiviruses and the potency test have been carried out on batch A044CD01-10 (final batch A044C).

I. Lemke

Dr. Ingun Lemke