

Manufacturer's Batch Protocol

Product: Bovilis IBR marker live

Batch: A043BE01

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: **73 673**

Number of containers the release is applied for: **73 673**

Number of doses per container: **50**

Number of samples for the competent authority: **-**

Date of expiry: **Feb-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-Oct-2014/s1

1103291450/10

Manufacturer's Batch Protocol

Product: Bovilis IBR marker live

Batch: A043BE01

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:	A043BE01
Batch number of final bulk:	A043 *
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:	06-Feb-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 A043B, material number 007375, containing CD stabilizer

Name:
Function:
Date:
Signature:

P.G. Mooren
Qualified Person
29 OCT 2014


Manufacturer's Batch Protocol

Product: Bovilis IBR marker live

Batch: A043BE01

FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
		<u>Sterility (FPC-01)</u>
20-Jan-2014	03-Feb-2014	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		<u>Mycoplasmas (FPC-02)</u>
03-Jan-2012	31-Jan-2012	Tested according to Ph. Eur. 2.6.7 Result: No mycoplasma detected Threshold: No mycoplasma detected Conclusion: Passed
		<u>Titration BHV-1(TCID50) (FPC-05)</u>
06-Feb-2014	10-Feb-2014	Tested according to Ph. Eur. 0696 Result: 8.2 / 8.5 / 8.5 log 10/VL Average: 8.4 log 10/VL Threshold: 5.7 – 7.3 log 10/dose Conclusion: Passed
		<u>Marker aspect (FPC-07)</u>
24-Jul-2012	21-Aug-2012	Result: No IBR GE- specific antibodies detected Threshold: No IBR GE- specific antibodies detected Conclusion: Passed
		<u>Extraneous agents (in vitro) (FPC-04)</u>
17-Jan-2012	02-Feb-2012	Tested according to Ph. Eur. 0696 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		<u>Identification (FPC-06)</u>
03-Aug-2012	03-Aug-2012	Result: Identity conform Threshold: Identity conform Conclusion: Passed

Manufacturer's Batch Protocol

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FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
		<u>Residual moisture (FPC-08)</u>
20-Jan-2014	20-Jan-2014	Tested according to Ph. Eur. 2.5.32 Result: 1.9 % Threshold: 0.4 – 4.0 % Conclusion: Passed
		<u>Vacuum (FPC-09)</u>
16-Jan-2014	16-Jan-2014	Result: Conform Threshold: All vials must pass the vacuum test Conclusion: Passed
		<u>Capcode (FPC-09)</u>
16-Jan-2014	16-Jan-2014	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

Manufacturer's Batch Protocol

Product: Bovilis IBR marker live

Batch: A043BE01

PRODUCTION INFORMATION

<u>Component</u>	<u>Batch</u>	<u>Site(s) of manufacturing</u>
Antigen	See composition table	Intervet, De Bilt, 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:

<u>Production step</u>	<u>Start</u>	<u>End</u>	<u>Volume</u>
Batch A043			
Seed:	17-Nov-2011	17-Nov-2011	8.9 ml /RCB
Harvest:	21-Nov-2011	21-Nov-2011	303 kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number:	A043*
Start date:	21-Nov-2011
End date:	21-Nov-2011
Total volume:	414 kg

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COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total Kg	Final Concentration (w/w)
IBR antigen	A043	303 Kg	73 %
CD Stabilizer	BMGM115731 BMGM117861	111 Kg	27 %

* Bulk batch number A043, material number 007375, containing CD stabilizer

FILLING

Batch number of final bulk: **A043**
Final batch number: **A043B**
Start date: **10-Jan-2014**
End date: **10-Jan-2014**
Filled containers: **73673**
Volume filled: **2 ml**

LYOPHILISATION:

Final batch number: **A043B**
Start date: **10-Jan-2014**
End date: **12-Jan-2014**
Number of containers: **73673**

IN PROCESS CONTROLS (antigen containing component)

In process controls IBR Antigen:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Batch A043 Sterility	01-Dec-2011	15-Dec-2011	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	10-Jan-2014	10-Jan-2014	2.00 ml	1.8-2.2 ml	Passed
Freeze drying	10-Jan-2014	12-Jan-2014	Within spec.	Within spec.	Passed

**MSD**

Animal Health

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

Intervet International bv

P.O. Box 31

5830 AA Boxmeer

The Netherlands

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F +31 485 56 8111

msd-animal-health.com

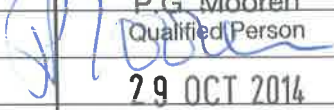
Notification of the intention to market a batch of an immunological veterinary medicinal product, which has a marketing authorisation in the following EC/EEA Member State Hungary and has received an EC Batch release certificate after OBPR or OCABR in another Member State in accordance with Article 81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

Trade name in the above mentioned Member State:	Bovilis 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):	A043
Final lot number:	A043B
Packaging lot number (if different from final lot n°):	A043BE01
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:	3 600
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Feb-2017

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	Art. 82 (OCABR)
Official batch release certificate number:	20170/14

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:	29 OCT 2014

----- 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:	

29-Oct-2014/as

EDQM ♦ OCABR/OBPR of IVMPS 2010

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: 20170/14

Date of Release of Certificate: 31.07.2014

**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	A043 A043B A043BE01-10
Batch number of diluent (where appropriate):	-
Type of container:	glass vials
Total number of containers of this batch:	73,673
Number of doses/volume per container:	50
Date of start of period of validity:	06.02.2014
Expiry date:	01.2017

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.



Mr. Rolf Beckmann





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	A043 A043B A043BE01-10
Expiry date:	01.2017

Results:

Method (SOP):	Appearance (S-31)
Test dates:	24.07.2014
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:	11.07. - 16.07.2014 / 30.07.2014
Results:	- Virus content 7.3 log ₁₀ TCID ₅₀ /dose. - BVDV-PCR negative.
Specifications	- Virus content 5.7 - 7.3 log ₁₀ TCID ₅₀ /dose. - No specifications for a BVDV-PCR.

Remarks/further tests:

The results for potency and for extraneous pestiviruses have been obtained on batch no. A043BE01-10 (final lot no. A043B).

Mr. Rolf Beckmann



Paul-Ehrlich-Institut Postfach 63207 Langen

Intervet Deutschland GmbH
Feldstraße 1a
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Aktenzeichen: 4/3: 2.03.01.0093
Ihr Zeichen:

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12.08.2014

Bovilis IBR-Marker live, Zul.-Nr. PEI.V.11616.01.1
Änderung des Bescheides über die staatliche Chargenfreigabe
Hier: Änderung des Verwendbarkeitsdatums

Sehr geehrte Damen und Herren,

der Bescheid über die Freigabe der Charge A043BE01-10 des Mittels Bovilis IBR-Marker live, Zul.-Nr. PEI.V.11616.01.1, vom 31.07.2014 (B.-Nr. 20170/14) wird geändert.

Die Charge ist verwendbar bis 01.2016.

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 

