MSD
Animal Health

Intervet International bv
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msd-animal-health.com

Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

MEMBER STATE SPECIFIC INFORMATION

Member state:	**HUNGARY**

Antigen containing component:

Trade name:	**Bovilis IBR Marker Inac vakcina A.U.V.**
Marketing authorisation number:	
Target species:	**Cattle**
Total number of containers in this batch:	**23 760**
Number of containers the release is applied for:	**23 760**
Number of doses per container:	**10**
Number of samples for the competent authority:	-
Date of expiry:	**Jun-2015**
Name and address of Marketing Authorisation Holder:	**Intervet Nederland B.V.** **Wim de Körverstraat 35** **5831 AN BOXMEER** **THE NETHERLANDS,** **represented by the local company**

13-Jan-2015/RD
1103499664/10

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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Infectious bovine rhinotracheitis vaccine (inactivated).**
Batch number of finished product:	**A025A01**
Batch number of final bulk:	**A025**
Pharmaceutical form of finished product:	**Suspension for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**05-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:
Function:
Date:
Signature:

S.T.M. Verstegen
Qualified Person
13 JAN 2015

Trade register No: 16028015

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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (FPC-01)
04-Jun-2013	25-Jun-2013	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		Inactivation (FPC-02)
28-Jun-2013	11-Jul-2013	Tested according to Ph. Eur. 0062 Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using mice (FPC-07)
05-Jun-2013	24-Jul-2013	Result: Conform Threshold: Conform Conclusion: Passed
		Potency IBR marker inac (VN)
		Single result: 9 / 10 / 9 / 8 / 9 / 8 / 9 / 10 / 8 / 9 Log 2 Average: 8.9 Log 2 Threshold: 6.1 - 11.1 Log 2 Conclusion: Passed
		Aluminium (FPC-04)
02-Sep-2013	02-Sep-2013	Tested according to Ph. Eur. 2.5.13 Result: 3.7 mg/ml Threshold: 3.0 - 4.4 mg/ml Conclusion: Passed
		Free formaldehyde (FPC-05)
20-Aug-2013	20-Aug-2013	Tested according to Ph. Eur. 2.4.18 Result: 0.04 % Threshold: 0.03 - 0.05 % Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		pH (FPC-03)
10-Sep-2013	10-Sep-2013	Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 6.0 - 8.0 Conclusion: Passed
		Marker property (FPC-08)
15-Jul-2013	16-Jul-2013	Result: No IBR-GE specific antibodies detected Threshold: No IBR-GE specific antibodies detected Conclusion: Passed
		Identity BHV-1 (FPC-08)
26-Jul-2013	02-Aug-2013	Result: Identity conform Threshold; Identity conform Conclusion: Passed
		Appearance (FPC-09)
29-May-2013	29-May-2013	Result: Conform Threshold: Pink turbid solution Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
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:

Production step	Start	End	Volume
Batch BIMI1204			
Seed:	25-May-2012	25-May-2012	0.003 MOI
Harvest:	30-May-2012	30-May-2012	474 Kg
Inactivation:	30-May-2012	30-May-2012	497 Kg
Concentration:	04-Jun-2012	04-Jun-2012	45 Kg
Batch BIMI1205			
Seed:	01-Jun-2012	01-Jun-2012	0.003 MOI
Harvest:	06-Jun-2012	06-Jun-2012	467 Kg
Inactivation:	06-Jun-2012	06-Jun-2012	487 Kg
Concentration:	11-Jun-2012	11-Jun-2012	44 Kg

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A025**
Start date: **22-May-2013**
End date: **23-May-2013**
Total volume: **1250.6 kg**

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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. *Batch:A025A01*

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BIMI1204 BIMI1205	53.6 kg	49.8 %
Excipient	BMGM302621 0000219280 0000246081 0000236798	568.8 kg	
Adjuvant	0000249965 0000229747 0000249962	626.7 kg	50.1 %
Preservative	0000234985	1.5 kg	0.12 %

FILLING

Batch number of final bulk: **A025**
Final batch number: **A025A**
Start date: **27-May-2013**
End date: **27-May-2013**
Filled containers: **23 760**
Volume filled: **20 ml**

IN PROCESS CONTROLS

In process controls IBR Antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BIMI1204					
Inactivation	08-Jun-2012	21-Jun-2012	Inactivated	Inactivated	Passed
Antigen content	12-Jun-2012	12-Jun-2012	679 EU/ml	N.a.	Passed
Sterility	19-Jun-2012	10-Jul-2012	no growth	no growth	Passed
Batch BIMI1205					
Inactivation	08-Jun-2012	21-Jun-2012	Inactivated	Inactivated	Passed
Antigen content	15-Jun-2012	15-Jun-2012	773 EU/ml	N.a.	Passed
Sterility	19-Jun-2012	10-Jul-2012	no growth	no growth	Passed

In process controls Final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	27-May-2013	27-May-2013	21 g	20.4-24 g	Passed

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: 4/3:2.03.01.0096
Reference Number: 4053/14
Date of Release of Certificate: 09.07.2014

EU/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 inac
International non-proprietary Name / Ph. Eur. name / common name:	Infectious bovine rhinotracheitis 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)	PEI.V.03246.01.1
Manufacturer`s batch number(s): - final bulk no - final lot no - packaging lot no	 A025 A025A A025A01-10
Batch number of diluent (where appropriate):	-
Type of container:	PET bottles
Total number of containers of this batch:	23,760
Number of doses/volume per container:	10
Date of start of period of validity:	05.06.2013
Expiry date:	05.2015

DAkkS Deutsche Akkreditierungsstelle D-PL-13085-02-00

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

PAUL-EHRLICH-INSTITUT LANGEN
9

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

Paul-Ehrlich-Institut

AUTHORITY'S TEST REPORT

Trade name:	Bovilis IBR Marker inac
Marketing authorisation number:	PEI.V.03246.01.1
Manufacturer's batch number(s): -final bulk no -final lot no -packaging lot no	 A025 A025A A025A01-10
Expiry date:	05.2015

Results:

Method (SOP):	Appearance (S-31)
Test dates:	12.06.20174
Results:	Conform to specifications.
Specifications:	Pink turbid suspension.

Results:

Method (SOP):	Potency test (4/3-A-019)
Test dates:	05.12.2013 - 05.02.2014 / 20.02. - 16.04.2014
Results:	Seroconversion of 10/10 mice Individual results: 6; 7; 7; 6; 7; 6; 6; 7; 6; 5 Mean SN titre = 6.3 log2 (first test run = OOS; mean SN-titre = 4.6 and 4.5 log2)
Specifications	Seroconversion of 08/10 mice Mean SN titre 6.1-11.1 log2 VN units

Remarks/further tests:

Potency test results have been obtained on batch A025A01-10 (final bulk A025).

D. Lemke

Dr. Ingun Lemke

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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 Inac vakcina A.U.V.
International non-proprietary name / Ph. Eur. name / common name:	Infectious bovine rhinotracheitis 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:	2067/1-5/06 ÁOGYTI
Identification numbers associated with the lot to be marketed in the above mentioned Member State;	
Bulk number (final formulated bulk):	**A025**
Final lot number:	**A025A**
Packaging lot number (if different from final lot n°):	**A025A01**
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:	100
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Jun-2015

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	Art. 82 (OCABR)
Official batch release certificate number:	4053/14

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.

S.T.M. Verstegen
Qualified Person
13 JAN 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:	

13-Jan-2015/RD

EDQM ♦ OCABR/OBPR of IVMPS 2010

Trade register No: 16028015