

Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. Batch:A024B02

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: **7 128**
Number of containers the release
is applied for: **7 128**
Number of doses per container: **50**
Number of samples for the
competent authority: **-**
Date of expiry: **Apr-2015**
Name and address of Marketing
Authorisation Holder: **Intervet Nederland B.V.**
Wim de Körverstraat 35
5831 AN BOXMEER
THE NETHERLANDS,
respresented by the local
company

12-Feb-2014/as

1102951554/10

Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vaccina A.U.V. Batch:A024B02

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	Infectious bovine rhinotracheitis vaccine (inactivated).
Batch number of finished product:	A024B02
Batch number of final bulk:	A024
Pharmaceutical form of finished product:	Suspension for injection
Type of final container:	PET bottles
Date of start of period of validity:	16-Apr-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
25 FEB 2014


Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. Batch:A024B02

FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
08-Apr-2013	29-Apr-2013	<u>Sterility (FPC-01)</u> Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
19-Apr-2013	02-May-2013	<u>Inactivation (FPC-02)</u> Tested according to Ph. Eur. 0062 Result: Inactivated Threshold: Inactivated Conclusion: Passed
16-Apr-2013	04-Jun-2013	<u>Potency using mice (FPC-07)</u> Result: Conform Threshold: Conform Conclusion: Passed
		<u>Potency IBR marker inac (VN)</u> Single result: 8 / 8 / 10 / 9 / 8 / 8 / 7 / 8 / 7 / 9 Log 2 Average: 8.2 Log 2 Threshold: 6.1 – 11.1 Log 2 Conclusion: Passed
15-Aug-2013	15-Aug-2013	<u>Aluminium (FPC-04)</u> Tested according to Ph. Eur. 2.5.13 Result: 3.8 mg/ml Threshold: 3.0 – 4.4 mg/ml Conclusion: Passed
04-Jul-2013	04-Jul-2013	<u>Free formaldehyde (FPC-05)</u> Tested according to Ph. Eur. 2.4.18 Result: 0.04 % Threshold: 0.03 – 0.05 % Conclusion: Passed

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FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
12-Apr-2013	12-Apr-2013	<u>pH (FPC-03)</u> Tested according to Ph. Eur. 2.2.3 Result: 7.5 Threshold: 6.0 – 8.0 Conclusion: Passed
16-May-2013	17-May-2013	<u>Marker property (FPC-08)</u> Result: No IBR-GE specific antibodies detected Threshold: No IBR-GE specific antibodies detected Conclusion: Passed
07-Jun-2013	14-Jun-2013	<u>Identity BHV-1 (FPC-08)</u> Result: Identity conform Threshold; Identity conform Conclusion: Passed
29-Mar-2013	29-Mar-2013	<u>Appearance (FPC-09)</u> Result: Conform Threshold: Pink turbid solution Conclusion: Passed

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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 BIM1201			
Seed:	27-Apr-2012	27-Apr-2012	0.003 MOI
Harvest:	02-May-2012	02-May-2012	387 kg
Inactivation:	02-May-2012	02-May-2012	408 kg
Concentration:	07-May-2012	07-May-2012	33 kg
Batch BIM1202			
Seed:	04-May-2012	04-May-2012	0.003 MOI
Harvest:	09-May-2012	09-May-2012	467 kg
Inactivation:	09-May-2012	09-May-2012	490 kg
Concentration:	14-May-2012	14-May-2012	44.6 kg
Batch BIM1204			
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

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CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **A024**
Start date: **26-Mar-2013**
End date: **27-Mar-2013**
Total volume: **1253.1 kg**

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	BIMI1201	81.5 kg	50.0 %
	BIMI1202		
	BIMI1204		
Excipient	BMGM207831	544.5 kg	50.0 %
	0000203316		
	0000219280		
	0000221348		
Adjuvant	0000236798	625.6 kg	49.9 %
	0000226029		
Adjuvant	0000229747	625.6 kg	49.9 %
	0000226029		
Preservative	0000234985	1.5 kg	0.12 %

FILLING

Batch number of final bulk: **A024**
Final batch number: **A024B**
Start date: **28-Mar-2013**
End date: **28-Mar-2013**
Filled containers: **7 128**
Volume filled: **100 ml**

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IN PROCESS CONTROLS

In process controls IBR Antigen:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Batch BIM1201					
Inactivation	07-May-2012	21-May-2012	Inactivated	Inactivated	Passed
Antigen content	11-May-2012	11-May-2012	398 EU/ml	N.a.	Passed
Sterility	11-May-2012	01-Jun-2012	no growth	no growth	Passed
Batch BIM1202					
Inactivation	14-May-2012	31-May-2012	Inactivated	Inactivated	Passed
Antigen content	16-May-2012	16-May-2012	484 EU/ml	N.a.	Passed
Sterility	22-May-2012	12-Jun-2012	no growth	no growth	Passed
Batch BIM1204					
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

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	28-Mar-2013	28-Mar-2013	104 g	102-105 g	Passed

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 Directive 2004/28/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):	A024
Final lot number:	A024B
Packaging lot number (if different from final lot n°):	A024B02
Batch number of diluent: (where appropriate)	-
Type of Container:	Pet bottles
Number of doses/volume of container:	50
Total number of containers to be marketed in the above noted Member State:	360
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Apr-2015

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	Art. 82 (OCABR)
Official batch release certificate number:	6634/13

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):	 S.T.M. Verstegen Qualified Person 25/FEB 2014
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:	

25-Feb-2014/as

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: 6634/13
Date of Release of Certificate: 11.12.2013

**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	A024 A024B A024B01-10
Batch number of diluent (where appropriate):	-
Type of container:	PET bottles
Total number of containers of this batch:	7,128
Number of doses/volume per container:	50
Date of start of period of validity:	16.04.2013
Expiry date:	03.2015





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 



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	A024 A024B A024B01-10
Expiry date:	03.2015

Results:

Method (SOP):	Appearance (S-31)
Test dates:	02.10.2013
Results:	Conform to specifications.
Specifications:	Pink turbid suspension.

Results:

Method (SOP):	Potency test (4/3-A-019)
Test dates:	17.10. - 11.12.2013
Results:	Seroconversion of 10/10 mice Individual results: 6; 8; 8; 7; 6; 8; 9; 8; 7; 6 Mean SN titre = 7.3 log ₂
Specifications	Seroconversion of 10/10 mice Mean SN titre 6.1-11.1 log ₂ VN units

Remarks/further tests:

Potency test results have been obtained on batch A024A01-10 (final bulk A024).
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Dr. Ingun Lemke

