MSD
Animal Health

Intervet International bv
P.O. Box 31
5830 AA Boxmeer
The Netherlands
T +31 485 58 7600
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msd-animal-health.com

Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. Batch:A024B01

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**

30-Oct-2013/as
1102806480/10

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Infectious bovine rhinotracheitis vaccine (inactivated).**
Batch number of finished product:	**A024B01**
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: P.G. Mooren
Function: Qualified Person
Date: 07 NOV 2013
Signature:

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Manufacturer's Batch Protocol

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FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (FPC-01)
08-Apr-2013	29-Apr-2013	Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		Inactivation (FPC-02)
19-Apr-2013	02-May-2013	Tested according to Ph. Eur. 0062 Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using mice (FPC-07)
16-Apr-2013	04-Jun-2013	Result: Conform Threshold: Conform Conclusion: Passed
		Potency IBR marker inac (VN)
		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
		Aluminium (FPC-04)
15-Aug-2013	15-Aug-2013	Tested according to Ph. Eur. 2.5.13 Result: 3.8 mg/ml Threshold: 3.0 – 4.4 mg/ml Conclusion: Passed
		Free formaldehyde (FPC-05)
04-Jul-2013	04-Jul-2013	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)

Date on	Date off	Test results
		pH (FPC-03)
12-Apr-2013	12-Apr-2013	Tested according to Ph. Eur. 2.2.3 Result: 7.5 Threshold: 6.0 – 8.0 Conclusion: Passed
		Marker property (FPC-08)
16-May-2013	17-May-2013	Result: No IBR–GE specific antibodies detected Threshold: No IBR-GE specific antibodies detected Conclusion: Passed
		Identity BHV-1 (FPC-08)
07-Jun-2013	14-Jun-2013	Result: Identity conform Threshold; Identity conform Conclusion: Passed
		Appearance (FPC-09)
29-Mar-2013	29-Mar-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:A024B01

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 BIMI1201			
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 BIMI1202			
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 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

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Product: Bovilis IBR Marker Inac vakcina A.U.V. Batch:A024B01

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 BIMI1202 BIMI1204	81.5 kg	50.0 %
Excipient	BMGM207831 0000203316 0000219280 0000221348 0000236798	544.5 kg	
Adjuvant	0000226029 0000229747	625.6 kg	49.9 %
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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Manufacturer's Batch Protocol

Product: Bovilis IBR Marker Inac vakcina A.U.V. Batch:A024B01

IN PROCESS CONTROLS

In process controls IBR Antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch BIMI1201					
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 BIMI1202					
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 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

In process controls Final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	28-Mar-2013	28-Mar-2013	104 g	102-105 g	Passed