

## Manufacturer's Batch Protocol

*Product: Bovilis IBR marker live*

*Batch: A042CB01*

### MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

#### Antigen containing component:

Trade name:	<b>Bovilis IBR marker live</b>
Marketing authorisation number:	
Target species:	<b>Cattle</b>
Total number of containers in this batch:	<b>67 211</b>
Number of containers the release is applied for:	<b>67 211</b>
Number of doses per container:	<b>10</b>
Number of samples for the competent authority:	<b>-</b>
Date of expiry:	<b>Oct-2016</b>
Name and address of Marketing Authorisation Holder:	<b>Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer THE NETHERLANDS, represented by the local company</b>

**29-Jan-2014/cc**

**1102907888/10**

## Manufacturer's Batch Protocol

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*Batch: A042CB01*

### 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:	A042CB01
Batch number of final bulk:	A042 *
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:	11-Oct-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.

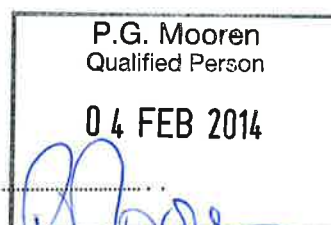
\*Bulk batch number A042, material number 007375, containing CD stabilizer

Name:

Function:

Date:

Signature: .....



Part II; Page 1 of 3

## Manufacturer's Batch Protocol

Product: *Bovilis IBR marker live*

Batch: A042CB01

### FINAL BATCH TESTING (FINISHED PRODUCT)

#### Antigen containing component:

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
09-Oct-2013	23-Oct-2013	<p><b><u>Sterility (FPC-01)</u></b>            Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1            Result: No growth            Threshold: No growth            Conclusion: Passed</p>
02-Dec-2011	30-Dec-2011	<p><b><u>Mycoplasmas (FPC-02)</u></b>            Tested according to Ph. Eur. 2.6.7            Result: No mycoplasma detected            Threshold: No mycoplasma detected            Conclusion: Passed</p>
11-Oct-2013	15-Oct-2013	<p><b><u>Titration BHV-1(TCID50) (FPC-05)</u></b>            Tested according to Ph. Eur. 0696            Result: 7.8 / 7.8 / 7.9 log 10/VL            Average: 7.8 log 10/VL            Threshold: 5.7 – 7.3 log 10/dose            Conclusion: Passed</p>
17-Jul-2012	14-Aug-2012	<p><b><u>Marker aspect (FPC-07)</u></b>            Result: No IBR GE- specific antibodies detected            Threshold: No IBR GE- specific antibodies detected            Conclusion: Passed</p>
20-Dec-2011	05-Jan-2012	<p><b><u>Extraneous agents (in vitro) (FPC-04)</u></b>            Tested according to Ph. Eur. 0696            Result: No extraneous agents detected            Threshold: No extraneous agents detected            Conclusion: Passed</p>
03-Aug-2012	03-Aug-2012	<p><b><u>Identification (FPC-06)</u></b>            Result: Identity conform            Threshold: Identity conform            Conclusion: Passed</p>

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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>
07-Oct-2013	07-Oct-2013	Tested according to Ph. Eur. 2.5.32 Result: 1.5 % Threshold: 0.4 – 4.0 % Conclusion: Passed
		<u>Vacuum (FPC-09)</u>
08-Oct-2013	09-Oct-2013	Result: Conform Threshold: All vials must pass the vacuum test Conclusion: Passed
		<u>Capcode (FPC-09)</u>
02-Oct-2013	02-Oct-2013	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

## Manufacturer's Batch Protocol

*Product: Bovilis IBR marker live*

*Batch:A042CB01*

### PRODUCTION INFORMATION

<u>Component</u>	<u>Batch</u>	<u>Site(s) of manufacturing</u>
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<sup>-</sup> BHV-1 virus strain Gk/D

MS-batch number: 211196

Last testing: 16-Oct-1997

Working seed material: gE<sup>-</sup> 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 A042			
Seed:	03-Nov-2011	03-Nov-2011	0.0116 ml/RCB
Harvest:	07-Nov-2011	07-Nov-2011	377.5 kg

### CREATION OF THE FINISHED PRODUCT

#### BLENDING OF FINAL BULK:

Batch number:	A042*
Start date:	07-Nov-2011
End date:	07-Nov-2011
Total volume:	515.9 kg

# Manufacturer's Batch Protocol

Product: *Bovilis IBR marker live*

Batch: *A042CB01*

## COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total Kg	Final Concentration (w/w)
IBR antigen	A042	377.5 Kg	73 %
CD Stabilizer	BMGM117861 BMGM115731	138.4 Kg	27 %

\* Bulk batch number A042, material number 007375, containing CD stabilizer

## FILLING

Batch number of final bulk: **A042**  
Final batch number: **A042C**  
Start date: **27-Sep-2013**  
End date: **27-Sep-2013**  
Filled containers: **67 211**  
Volume filled: **2 ml**

## LYOPHILISATION:

Final batch number: **A042C**  
Start date: **27-Sep-2013**  
End date: **29-Sep-2013**  
Number of containers: **67 211**

## 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 A042 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	27-Sep-2013	27-Sep-2013	2.0 ml	1.8-2.2 ml	Passed
Freeze drying	27-Sep-2013	29-Sep-2013	Within spec.	Within spec.	Passed

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

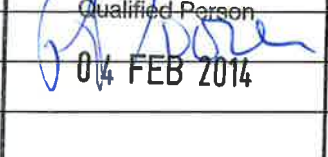
Notification of the intention to market a batch of an immunological veterinary medicinal product, which has a marketing authorisation in the following EC/EEA Member State Hungary and has received an EC Batch release certificate after OBPR or OCABR in another Member State in accordance with Article 81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

<b>Trade name in the above mentioned Member State:</b>	Bovilis IBR marker live
<b>International non-proprietary name / Ph. Eur. name / common name:</b>	Infectious bovine rhinotracheitis vaccine (live)
<b>Name and address of Marketing Authorisation Holder (MAH) for the above mentioned Member State:</b>	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer Represented by the local company
<b>Market authorisation number in the above mentioned Member State:</b>	2156/1-7/07 MgSzH ÁTI
<b>Identification numbers associated with the lot to be marketed in the above mentioned Member State:</b>	
<b>Bulk number (final formulated bulk):</b>	A042
<b>Final lot number:</b>	A042C
<b>Packaging lot number (if different from final lot n°):</b>	A042CB01
<b>Batch number of diluent: (where appropriate)</b>	-
<b>Type of Container:</b>	Hydrolytical class type I glass
<b>Number of doses/volume of container:</b>	10
<b>Total number of containers to be marketed in the above noted Member State:</b>	2700
<b>Proposed date of marketing:</b>	After approval batch release
<b>Assigned expiry date for this lot in the above noted Member State:</b>	Oct-2016

<b>CA/OMCL performing batch release:</b>	PEI
<b>Type of certificate: (i.e.: OCABR or OBPR)</b>	OCABR
<b>Official batch release certificate number:</b>	8460/13

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.

<b>Signature of qualified person (MAH):</b>	
<b>Name of qualified person (MAH):</b>	
<b>Date of issue:</b>	

----- Use of the following section is optional -----

**For completion by the CA/OMCL after submission:**

<b>Date received:</b>	
<b>Signature of qualified authority (CA/OMCL):</b>	
<b>Name of qualified authority (CA/OMCL):</b>	
<b>Decision and Date:</b>	

04-Feb-2014/ce

Paul-Ehrlich-Institut, Paul-Ehrlich-Str. 51-59, 63225 Langen

Intervet Deutschland GmbH  
Feldstraße 1a  
D - 85716 Unterschleißheim

Administrative Code: 4/3.2.03.01.0093

Reference Number: 8460/13

Date of Release of Certificate: 20.01.2014

**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	A042 A042C A042CB01-10
Batch number of diluent (where appropriate):	-
Type of container:	glass vials
Total number of containers of this batch:	67,211
Number of doses/volume per container:	10
Date of start of period of validity:	11.10.2013
Expiry date:	09.2016

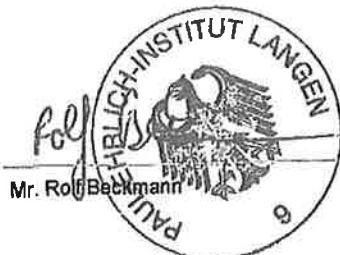
This batch has been examined using documented testing procedures that form part of a quality management system.

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	A042 A042C A042CB01-10
Expiry date:	09.2016

**Results:**

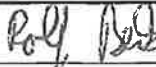
Method (SOP):	Appearance (S-31)
Test dates:	10.12.2013
Results:	Conform to specifications.
Specifications:	Pellet must be even. Colour must be without differences.

**Results:**

Method (SOP):	- Potency test (4/3-S-016) - Test for extraneous pestiviruses (BVDV-PCR)
Test dates:	15.01. - 20.01.2014 / 17.01.2014
Results:	- Virus content 7.0 log <sub>10</sub> TCID <sub>50</sub> /dose. - BVDV-PCR negative.
Specifications	- Virus content 5.7 - 7.3 log <sub>10</sub> TCID <sub>50</sub> /dose. - No specifications for a BVDV-PCR.

**Remarks/further tests:**

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Mr. Rolf Beckmann

