MSD
Animal Health

Intervet International bv
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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	**Avian viral tenosynovitis, infectious brochitis, infections bursal disease and Newcastle disease vaccine (inactivated).**
Batch number of finished product:	**D090A08**
Batch number of final bulk:	**D090**
Pharmaceutical form of finished product:	**Emulsion for injection**
Type of final container:	**PET bottles**
Date of start of period of validity:	**31-Jul-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: .....

P.G. Mooren
Qualified Person
26 FEB 2014

Trade register No: 16028015

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Sterility (F05)
29-Jul-2013	12-Aug-2013	Tested according to Ph. Eur. 0062 / Ph. Eur. 2.6.1 Result: No growth Threshold: No growth Conclusion: Passed
		Inactivation NDV
31-Jul-2013	12-Aug-2013	Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Inactivation IBV-M41
31-Jul-2013	12-Aug-2013	Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Inactivation IBDV
26-Jul-2013	26-Aug-2013	Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Inactivation Reo (F01a)
26-Jul-2013	26-Aug-2013	Result: Inactivated Threshold: Inactivated Conclusion: Passed
		Potency using chickens (F08)
31-Jul-2013	21-Aug-2013	Tested according to Ph. Eur. 0870 Result: Conform Threshold: Conform Conclusion: Passed
		Potency NDV (HI)
		Result: 7 / 5 / 6 / 7 / 7 / 7 / 6 / 6 / 6 / 7 Log 2 Average: 6.4 Log 2 Threshold: >= 4.0 Log 2 Conclusion: Passed
		Identity NDV
		Tested according to Ph. Eur. 0870 Result: Identity conform Threshold: Identity conform Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
31-Jul-2013	11-Sep-2013	**Potency using chickens (F08)** Tested according to Ph. Eur. 0959 and 0960 Result: Conform Threshold: Conform Conclusion: Passed
		Potency Reo (EIA) Result: 9.4/8.2/10.7/8.0/7.4/5.7/7.4/8.2/8.8/7.5 Log 2 Average: 8.1 Log 2 Threshold: >= 7.4 Log 2 Conclusion: Passed
		Identity Reo Result: Identity conform Threshold: Identity conform Conclusion: Passed
		Potency IBV-M41 (HI) Result: 8 / 8 / 4 / 8 / 5 / 9 / 9 / 8 / 9 / 9 Log 2 Average: 7.7 Log 2 Threshold: >= 6.0 Log 2 Conclusion: Passed
		Identity IBV-M41 Tested according to Ph. Eur. 0959 Result: Identity conform Threshold: Identity conform Conclusion: Passed
		Potency IBDV (VN) Result: 14/15/17/16/14/16/16/14/15/14 Log 2 Average: 15.1 Log 2 Threshold: >= 14.5 Log 2 Conclusion: Passed
		Identity IBDV Tested according to Ph. Eur. 0960 Result: Identity conform Threshold: Identity conform Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

FINAL BATCH TESTING (FINISHED PRODUCT)

Date on	Date off	Test results
		Extraneous agents (F07)
31-Jul-2013	04-Sep-2013	Tested according to Ph. Eur. 0870, 0959 and 0960 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		Visual appearance (F06)
12-Aug-2013	12-Aug-2013	Result: Conform Threshold: Homogeneous, no breaking, white to nearly white emulsion Conclusion: Passed
		Type of emulsion (F06)
14-Aug-2013	14-Aug-2013	Result: Water in oil Threshold: Water in oil Conclusion: Passed
		Viscosity (F06)
14-Aug-2013	14-Aug-2013	Tested according to Ph. Eur. 2.2.10 Result: 124 cP Threshold: < 450 cP Conclusion: Passed
		Pharmaceutical stability (F06)
26-Jul-2013	16-Aug-2013	Result: Stable Threshold: Stable Conclusion: Passed
		Free formaldehyde (F06)
28-Aug-2013	28-Aug-2013	Tested according to Ph. Eur. 2.4.18 Result: 0.02 % Threshold: <= 0.05 % Conclusion: Passed
		Final inspection (F10)
12-Aug-2013	12-Aug-2013	Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

PRODUCTION INFORMATION

Component	Batch	Site(s) of manufacturing
Antigen IB M41	See composition table	Intervet Salamanca, SPAIN
Antigen Reo 1733	See composition table	Intervet Salamanca, SPAIN
Antigen Reo 2408	See composition table	Intervet Salamanca, SPAIN
Antigen IBDV D78	See composition table	Intervet Salamanca, SPAIN
Antigen NDV clone 30	See composition table	Intervet Salamanca, SPAIN
Bulk vaccin	See blending	Intervet Salamanca, SPAIN
Filled product	See filling	Intervet Salamanca, SPAIN

STARTING MATERIALS:

Virus seed lots:

Master seed material: **IBV strain M41**
MS-batch number: **8104247**
Date of last testing: **16-Mar-2004**

Working seed material: **IBV strain M41**
WS-batch number: **19J05**
Date of last testing: **27-Apr-2006**

Master seed material: **Reo strain 1733**
MS-batch number: **P4 112682**
Date of last testing: **28-Nov-1983**

Working seed material: **Reo strain 1733**
WS-batch number: **06E26**
Date of last testing: **01-Nov-2006**

Master seed material: **Reo strain 2408**
MS-batch number: **P4 120282**
Date of last testing: **18-Jan-1984**

Working seed material: **Reo strain 2408**
WS-batch number: **06F02-A**
Date of last testing: **18-Sep-2006**

Master seed material: **IBDV strain D78**
MS-batch number: **781211**
Date of last testing: **09-May-2003**

Working seed material: **IBDV strain D78**
WS-batch number: **99H10**
Date of last testing: **28-Mar-2003**

Master seed material: **NDV strain clone 30**
MS-batch number: **30 LS**
Date of last testing: **12-Mar-2004**

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

Virus seed lots:
Working seed material: **NDV strain clone 30**
WS-batch number: **003027A**
Date of last testing: **17-Oct-2003**

Eggs for production:
Supplier: **LOHMANN**
Flock no.: **50307**

Primary avian cells:
Date and result of SPF-testing: **08-Apr-2013 / PASSED**

Permanent cell line:
Master cell seed: **Vero cell line**
MCS-batch number: **111287**
Last testing: **29-Jun-1989**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF IBV M41 COMPONENT:

Production step	Start	End	Volume
Batch: SIBV12047			
Seed:	06-Aug-2012	06-Aug-2012	0.10 ml/egg
Harvest:	09-Aug-2012	10-Aug-2012	1279.39 L
Inactivation:	09-Aug-2012	10-Aug-2012	1289.80 L

PRODUCTION OF Reo 1733 COMPONENT:

Production step	Start	End	Volume
Batch SREO13008			
Seed:	29-Apr-2013	29-Apr-2013	4.00 ml
Harvest:	03-May-2013	03-May-2013	1396.00 L
Inactivation:	03-May-2013	05-May-2013	1469.90 L

PRODUCTION OF Reo 2408 COMPONENT:

Production step	Start	End	Volume
Batch SREO13005			
Seed:	08-Apr-2013	08-Apr-2013	4.00 ml
Harvest:	12-Apr-2013	12-Apr-2013	1401.02 L
Inactivation:	12-Apr-2013	14-Apr-2013	1475.40 L

PRODUCTION OF IBDV D78 COMPONENT:

Production step	Start	End	Volume
Batch SGBV12002			
Seed:	22-May-2012	22-May-2012	0.007 ml/rb
Harvest:	01-Jun-2012	01-Jun-2012	1168.20 kg
Inactivation:	01-Jun-2012	04-Jun-2012	1226.60 kg

Trade register No: 16028015

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

PRODUCTION OF IBDV D78 COMPONENT:

Production step	Start	End	Volume
Batch SGBV12003			
Seed:	29-May-2012	29-May-2012	0.007 ml/rb
Harvest:	08-Jun-2012	08-Jun-2012	1164.40 kg
Inactivation:	08-Jun-2012	11-Jun-2012	1222.60 kg

PRODUCTION OF NDV CLONE 30 COMPONENT:

Production step	Start	End	Volume
Batch SNDV13006			
Seed:	03-Jan-2013	03-Jan-2013	0.10 ml/egg
Harvest:	08-Jan-2013	09-Jan-2013	1362.66 L
Inactivation:	08-Jan-2013	09-Jan-2013	1372.80 L

CREATION OF THE FINISHED PRODUCT

BLENDING OF FINAL BULK:

Batch number: **D090**
Start date: **23-Jul-2013**
End date: **23-Jul-2013**
Total volume: **4000.04 kg**

COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active M41	SIBV12047	143.04 x 10^6 EU	45 %
Active Reo 1733	SREO13008	1587.96 x 10^6 EU	
Active Reo 2408	SREO13005	1583.57 x 10^6 EU	
Active Gumboro	SGBV12002, SGBV12003	4538.13 x 10^6 EU	
Active ND	SNDV13006	353.74 kg	
Excipient	0000000008	to 4000.04 kg	
Adjuvant	0000268569, 0000222901, 0000222342, 0000251025	2221.88 kg	55 %

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

FILLING

Batch number of final bulk:	**D090**
Final batch number:	**D090A**
Start date:	**24-Jul-2013**
End date:	**24-Jul-2013**
Filled containers:	**8 416**
Volume filled:	**500 ml**

IN PROCESS CONTROLS

In process controls IBV M41 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch SIBV12047					
Antigen content	14-Aug-2012	16-Aug-2012	298 EU/ml	>= 116 EU/ml	Passed
Inactivation	03-Sep-2012	13-Sep-2012	Inactivated	Inactivated	Passed
Sterility	31-Aug-2012	14-Sep-2012	No growth	No growth	Passed

In process controls Reo 1733 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch SREO13008					
Antigen content	22-May-2013	22-May-2013	4201 EU/ml	n.a.	Passed
Inactivation	24-May-2013	04-Jun-2013	Inactivated	Inactivated	Passed
Sterility	08-May-2013	29-May-2013	No growth	No growth	Passed

In process controls Reo 2408 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch SREO13005					
Antigen content	22-May-2013	22-May-2013	4828 EU/ml	n.a.	Passed
Inactivation	03-May-2013	14-May-2013	Inactivated	Inactivated	Passed
Sterility	17-Apr-2013	08-May-2013	No growth	No growth	Passed

In process controls IBDV D78 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch SGBV12002					
Antigen content	11-Jun-2012	11-Jun-2012	121279 EU/ml	n.a.	Passed
Inactivation	11-Jun-2012	29-Jun-2012	Inactivated	Inactivated	Passed
Sterility	26-Jul-2012	09-Aug-2012	No growth	No growth	Passed
Batch SGBV12003					
Antigen content	19-Jun-2012	19-Jun-2012	114275 EU/ml	n.a.	Passed
Inactivation	18-Jun-2012	06-Jul-2012	Inactivated	Inactivated	Passed
Sterility	26-Jul-2012	09-Aug-2012	No growth	No growth	Passed

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

In process controls ND clone 30 antigen:

Test	Start	End	Result	Thresholds	Conclusion
Batch SNDV13006					
Antigen content (HA)	10-Jan-2013	10-Jan-2013	10	>= 7 *	Passed
Inactivation	29-Jan-2013	12-Feb-2013	Inactivated	Inactivated	Passed
Sterility	30-Jan-2013	13-Feb-2013	No growth	No growth	Passed

* Log_2/0.05 ml

In process controls final product:

Test	Start	End	Result	Thresholds	Conclusion
Filling volume	24-Jul-2013	24-Jul-2013	514 ml	>= 510 ml	Passed

Trade register No. 16028015

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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:	Nobilis Reo+IB+G+ND
International non-proprietary name / Ph. Eur. name / common name:	Avian viral tenosynovitis, infectious brochitis, infections bursal disease and Newcastle disease 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:	2245/1/07 MgSzH ÁTI
Identification numbers associated with the lot to be marketed in the above mentioned Member State;	
Bulk number (final formulated bulk):	**D090**
Final lot number:	**D090A**
Packaging lot number (if different from final lot n°):	**D090A08**
Batch number of diluent: (where appropriate)	-
Type of Container:	PET bottles
Number of doses/volume of container:	1 000
Total number of containers to be marketed in the above noted Member State:	192
Proposed date of marketing:	After approval batch release
Assigned expiry date for this lot in the above noted Member State:	Jul-2015

CA/OMCL performing batch release:	PEI
Type of certificate: (i.e.: OCABR or OBPR)	Art. 82 (OCABR)
Official batch release certificate number:	6993/13

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.

P.G. Mooren
Qualified Person
26 FEB 2014

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:	

26-Feb-2014/sl

Trade register No: 16028015

1025912

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

Reference Number: 6993/13
Administrative Code 4/2:2.03.01.0056
Date of Release of Certificate 30.10.2013

EUROPEAN COMMUNITY/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:	Nobilis REO + IB + G + ND
International non-proprietary Name / Ph. Eur. name / common name:	-
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)	91a/94
Manufacturer's batch number(s): - final bulk no - final lot no - packaging lot no	 D090 D090A D090A01-10
Batch number of diluent (where appropriate):	-
Type of container:	PET bottles
Total number of containers of this batch:	8,416
Number of doses/volume per container:	1,000
Date of start of period of validity:	31.07.2013
Expiry date:	06.2015

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.

A. Motitschke

Dr. Andreas Motitschke

PAUL-EHRLICH-INSTITUT LANGEN

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

Paul-Ehrlich-Institut

AUTHORITY'S TEST REPORT

Trade name:	Nobilis REO + IB + G + ND
Marketing authorisation number:	91a/94
Manufacturer's batch number(s): -final bulk no -final lot no -packaging lot no	 D090 D090A D090A01-10
Expiry date:	06.2015

Results:

Method (SOP):	Appearance (4/2-S-044-02)
Test dates:	23.10.2013
Results:	No abnormality detected.
Specifications:	whitish emulsion

Results:

Method (SOP):	ND antigen ELISA (4/2-S-038-04)
Test dates:	28.10.2013
Results:	12,60 AU/dose 10,97 AU/dose (lower limit) 14,40 AU/dose (upper limit)
Specifications	≥ 1,5 AU/dose

Remarks/further tests:

A. Motitschke

Dr. Andreas Motitschke

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Manufacturer's Batch Protocol

Product: Nobilis Reo+IB+G+ND *Batch: D090A08*

MEMBER STATE SPECIFIC INFORMATION

Member state:	**Hungary**

Antigen containing component:

Trade name:	**Nobilis Reo+IB+G+ND**
Marketing authorisation number:	
Target species:	**Poultry**
Total number of containers in this batch:	**8 416**
Number of containers the release is applied for:	**8 416**
Number of doses per container:	**1 000**
Number of samples for the competent authority:	-
Date of expiry:	**Jul-2015**
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**

19-Feb-2014/cc
1103079090/10