



## Manufacturer's Batch Protocol

*Product: Bovilis BVD*

*Batch: A104A01*

### MEMBER STATE SPECIFIC INFORMATION

Member state: **HUNGARY**

#### Antigen containing component:

Trade name:	<b>Bovilis BVD</b>
Marketing authorisation number:	
Target species:	<b>Cattle</b>
Total number of containers in this batch:	<b>11 894</b>
Number of containers the release is applied for:	<b>11 894</b>
Number of doses per container:	<b>50</b>
Number of samples for the competent authority:	<b>-</b>
Date of expiry:	<b>Oct-2015</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>

**22-Aug-2014/s1**

**1103346395/10**

## Manufacturer's Batch Protocol

*Product: Bovilis BVD*

*Batch: A104A01*

### SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Common name of product:	<b>Bovine viral diarrhoea vaccine (inactivated).</b>
Batch number of finished product:	<b>A104A01</b>
Batch number of final bulk:	<b>A104</b>
Pharmaceutical form of finished product:	<b>Suspension for injection</b>
Type of final container:	<b>PET bottles</b>
Date of start of period of validity:	<b>08-Apr-2014</b>
Storage temperature:	<b>2-8° C</b>
Name and address of manufacturer:	<b>Intervet International B.V. Wim de Körverstraat 35 5831 AN BOXMEER NEDERLAND</b>
Name and address of the batch release site:	<b>Intervet International B.V. Wim de Körverstraat 35 5831 AN BOXMEER NEDERLAND</b>

### 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  
29 AUG 2014  


## Manufacturer's Batch Protocol

*Product: Bovilis BVD*

*Batch: A104A01*

### FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
15-Apr-2014	06-May-2014	<p><b><u>Sterility (F09)</u></b> Tested according to Ph. Eur. 0062/Ph.Eur.2.6.1. Result: No growth Threshold: No growth Conclusion: Passed</p>
16-May-2014	28-May-2014	<p><b><u>Inactivation (F03)</u></b> Result: Inactivated Threshold: Inactivated Conclusion: Passed</p>
08-Apr-2014	27-May-2014	<p><b><u>Potency using mice (F11)</u></b> Result: Conform Threshold: Conform Conclusion: Passed</p> <p><b><u>Potency BVDV (VN)</u></b> Single result: 8 / 9 / 9 / 9 / 6 / 10 Log 2 Average: 8.5 Log 2 Threshold: &gt;= 5.6 Log 2 Conclusion: Passed</p>
06-May-2014	06-May-2014	<p><b><u>Methyl parahydroxybenzoate (F08)</u></b> Result: 1.5 mg/mL Threshold: 1.2 – 1.8 mg/mL Conclusion: Passed</p>
05-May-2014	05-May-2014	<p><b><u>Aluminium (F08)</u></b> Tested according to Ph. Eur. 2.5.13 Result: 3.6 mg/mL Threshold: 3.0 – 4.5 mg/mL Conclusion: Passed</p>
22-Apr-2014	22-Apr-2014	<p><b><u>pH (F08)</u></b> Tested according to Ph. Eur. 2.2.3 Result: 7.4 Threshold: 7.0 – 7.8 Conclusion: Passed</p>

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### FINAL BATCH TESTING (FINISHED PRODUCT)

<u>Date on</u>	<u>Date off</u>	<u>Test results</u>
07-Apr-2014	07-Apr-2014	<u>Visual appearance (F08)</u> Result: Conform Threshold: Pink turbid suspension Conclusion: Passed
07-Apr-2014	07-Apr-2014	<u>Final inspection (F13)</u> Result: Correct cap code Threshold: Correct cap code Conclusion: Passed

## Manufacturer's Batch Protocol

*Product: Bovilis BVD*

*Batch: A104A01*

### PRODUCTION INFORMATION

<u>Component</u>	<u>Batch</u>	<u>Site(s) of manufacturing</u>
Antigen	See composition table	Intervet, Salamanca, Spain
Bulk vaccin	see blending	Intervet, Boxmeer, the Netherlands
Filled product	see filling	Intervet, Boxmeer, the Netherlands

### STARTING MATERIALS:

#### Virus seed lots:

Master seed material: **BVD virus strain C86**

MS-batch number: **F22.4.91**

Date of last testing: **25-AUG-1994**

Working seed material: **BVD virus strain C86**

WS-batch number: **27D09**

Date of last testing: **10-Jul-2009**

#### Permanent cell line:

Master cell seed: **JCK cell line**

MCS-batch number: **JCK 56° MCS/3**

Date of last testing: **11-MAY-1999**

### INTERMEDIATE STAGES OF PRODUCTION

#### PRODUCTION OF BVD COMPONENT:

<u>Production step</u>	<u>Start</u>	<u>End</u>	<u>Volume</u>
Batch SBVD13008			
Seed:	25-Oct-2013	25-Oct-2013	0.03 ml/rb
Harvest:	31-Oct-2013	31-Oct-2013	693.00 kg
Inactivation:	31-Oct-2013	31-Oct-2013	707.10 kg
Batch SBVD13009			
Seed:	01-Nov-2013	01-Nov-2013	0.03 ml/rb
Harvest:	07-Nov-2013	07-Nov-2013	698.00 kg
Inactivation:	07-Nov-2013	07-Nov-2013	712.20 kg

### CREATION OF THE FINISHED PRODUCT

#### BLENDING OF FINAL BULK:

Batch number:	<b>A104</b>
Start date:	<b>25-Mar-2014</b>
End date:	<b>26-Mar-2014</b>
Total volume:	<b>1251.2 kg</b>

## Manufacturer's Batch Protocol

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Batch: *A104A01*

### COMPOSITION OF THE FINAL BULK

Components	Batch no.	Total units	Final concentration
Active	SBVD13008 SBVD13009	39.10 kg	3.13 %
Adjuvant	0000284049 0000284050	625.50 kg	50.00 %
Excipient	0000257120 0000275655 BMGM400601 0000275652	584.74 kg	46.73 %
Preservative	0000198409	1.88 kg	0.15 %

### FILLING

Batch number of final bulk: **A104**  
Final batch number: **A104A**  
Start date: **02-Apr-2014**  
End date: **02-Apr-2014**  
Filled containers: **11 894**  
Volume filled: **100 ml**

### IN PROCESS CONTROLS

#### In process controls BVD antigen:

<u>Test</u>	<u>Start</u>	<u>End</u>	<u>Result</u>	<u>Thresholds</u>	<u>Conclusion</u>
Batch SBVD13008					
Antigen content	28-Nov-2013	28-Nov-2013	712 EU/ml	n.a.	Passed
Inactivation	08-Nov-2013	20-Nov-2013	Inactivated	Inactivated	Passed
Sterility	06-Nov-2013	27-Nov-2013	No growth	No growth	Passed
Batch SBVD13009					
Antigen content	28-Nov-2013	28-Nov-2013	826 EU/ml	n.a.	Passed
Inactivation	15-Nov-2013	27-Nov-2013	Inactivated	Inactivated	Passed
Sterility	12-Nov-2013	03-Dec-2013	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	02-Apr-2014	02-Apr-2014	103 ml	>= 102 ml	Passed