

Manufacturer's Batch Protocol

Product: Nobivac Parvo-C

Batch: A090B01

MEMBER STATE SPECIFIC INFORMATION

Member state: **Hungary**

Antigen containing component:

Trade name: **Nobivac Parvo-C**

Marketing authorisation number:

Target species: **Dogs**

Total number of containers in
this batch: **85 309**

Number of containers the release
is applied for: **85 309**

Number of doses per container: **1**

Number of samples for the
competent authority: **-**

Date of expiry: **Mar-2017**

Name and address of Marketing
Authorisation Holder: **Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands,
represented by the local
company**

16-Mar-2015/as
1103613391/10

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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Antigen containing component:


| | |
|--|---|
| Common name of product: | Canine parvovirus vaccine (live). |
| Batch number of finished product: | A090B01 |
| Batch number of final bulk: | A090 |
| Pharmaceutical form of finished product: | Lyophilisate + solvent for a suspension for injection |
| Type of final container: | Hydrolytic class type I glass |
| Date of start of period of validity: | 06-Mar-2015 |
| 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 23 MAR 2015  |
|---|

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FINAL BATCH TESTING (FINISHED PRODUCT)

Antigen containing component:

| <u>Date on</u> | <u>Date off</u> | <u>Test results</u> |
|----------------|-----------------|--|
| 26-May-2014 | 09-Jun-2014 | <u>Sterility test (F10)</u> Tested according to Ph. Eur. 0062 / Ph. Eur. 2.6.1. Result: No growth Threshold: No growth Conclusion: Passed |
| 20-May-2014 | 17-Jun-2014 | <u>Mycoplasmas (F11)</u> Tested according to Ph. Eur. 2.6.7 Result: No growth Threshold: No growth Conclusion: Passed |
| 18-Jul-2014 | 28-Jul-2014 | <u>Titration of CPV (TCID50) (F13)</u> Result: 7.67 / 7.83 / 7.50 Log10/VL Average: 7.7 Log10/VL Threshold: 7.0 – 8.4 Log 10/dose Conclusion: Passed |
| 18-Jun-2014 | 02-Jul-2014 | <u>Extraneous agents (F12)</u> Tested according to Ph. Eur. 0964 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed |
| 13-Jun-2014 | 18-Jun-2014 | <u>Identity CPV</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed |
| 20-May-2014 | 20-May-2014 | <u>Residual moisture (F15)</u> Tested according to Ph. Eur. 2.5.32 Result: 1.5 % Threshold: <= 4.0 % Conclusion: Passed |
| 16-May-2014 | 16-May-2014 | <u>Final inspection (F18)</u> Result: Correct cap code Threshold: Correct cap code Conclusion: Passed |

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PRODUCTION INFORMATION

| <u>Component</u> | <u>Batch</u> | <u>Site(s) of manufacturing</u> |
|------------------|-----------------------|------------------------------------|
| Antigen CPV | 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: **CPV strain**
MS-batch number: **071790TMS**
Date of last testing: **19-APR-1996**

Working seed material: **CPV strain**
WS-batch number: **12L08**
Date of last testing: **02-Mar-2009**

Permanent cell line:

Master cell seed: **A72 cell line**
MCS-batch number: **PSA-5**
Date of last testing: **24-JUN-1996**

INTERMEDIATE STAGES OF PRODUCTION

PRODUCTION OF CPV COMPONENT:

| <u>Production step</u> | <u>Start</u> | <u>End</u> | <u>Volume</u> |
|------------------------|--------------|-------------|---------------|
| Batch BCPA3101 | | | |
| Seed: | 15-Apr-2013 | 15-Apr-2013 | 54 ml |
| Harvest: | 19-Apr-2013 | 19-Apr-2013 | 491 kg |

CREATION OF THE FINISHED PRODUCT

BLENDING OF THE FINAL BULK:

Batch number: **A090**
Start date: **09-May-2014**
End date: **09-May-2014**
Total volume: **157590 ml**

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COMPOSITION OF THE FINAL BULK

| Components | Batch no. | Calculated titre/dose | Final concentration |
|--------------|--|-----------------------|---------------------|
| CPV antigen | BCPA3101 | 7.51 | 16000 ml |
| Medium / FCS | BMGM405712 0000222942 0000256787 | | 102192 ml |
| Stabilizer | BMGM400821 BMGM400822 | | 39398 ml |

FILLING

Batch number of final bulk: **A090**
Final batch number: **A090B**
Start date: **13-May-2014**
End date: **13-May-2014**
Filled containers: **85309**
Volume filled: **0.5 ml**

LYOPHILISATION:

Final batch number: **A090B**
Start date: **13-May-2014**
End date: **14-May-2014**
Filled containers: **85309**

IN PROCESS CONTROLS (for antigen containing components)

In process controls CPV Antigen:

| <u>Test</u> | <u>Start</u> | <u>End</u> | <u>Result</u> | <u>Thresholds</u> | <u>Conclusion</u> |
|---------------------------------------|--------------|-------------|---------------------------|-------------------|-------------------|
| Batch BCPA3101 | | | | | |
| Sterility | 02-May-2013 | 16-May-2013 | no growth | no growth | Passed |
| Antigen content (TCID ₅₀) | 17-May-2013 | 27-May-2013 | 8.8 log ₁₀ /ml | n.a. | 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 | 13-May-2014 | 13-May-2014 | 0.50 ml | 0.45-0.55 ml | Passed |
| Freeze drying | 13-May-2014 | 14-May-2014 | Within spec. | Within spec. | Passed |