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|------------------------------------|--|---------------|----------|
| Bioveta, a.s. Ivanovice na Hané | Biocan Novel DHPPI, lyophilisate and solvent for suspension for injection for dogs | Ident. kód: | BPR00015 |
| | | Strana: | 1 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

1. SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

| | |
|---|--|
| Trade name | Biocan Novel DHPPI, lyophilisate and solvent for suspension for injection for dogs |
| Ph. Eur. | <i>Vaccina ad usum veterinarium.</i> |
| Nature of product | Vaccine against canine distemper (CDV), inf. hepatitis (CAV-1), inf. laryngotracheitis (CAV-2), parvovirus (CPV-2b), parainfluenza (CPIV-2) vivid. |
| Target species | Dog |
| Marketing authorisation number issued by (Member state/EU) | 3564/1/14 NÉBIH ÁTI (1 adag) |
| Batch number(s) of finished product | 05 53 22 |
| Type of final product | Lyophilisate and solvent for suspension for injection for dogs. |
| Type of final container | 3 ml glass vials |
| Total number of containers in this batch | 8 182 pcs |
| Number of containers the release is applied for | 330 x 10 x 1 d. |
| Number of doses per container | one dose of 1 ml |
| Number of samples for the competent authority | 25 x 1 ml |
| Date of start of period of validity (start of titration/potency test) | 14.11.2014 |
| Date of expiry | 26.10.2016 |
| Shelf life | 24 months |
| Storage temperature | Store in a dark and dry place at the temperature between 2 °C and 8 °C. Do not freeze. |
| Name and address of applicant | |
| Name and address of Marketing Authorisation holder if different | |
| Name and address of the batch control site | Bioveta, a.s. Komenského 212 683 23 Ivanovice na Hané, Czech Republic |

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| <p>Bioveta, a.s. Ivanovice na Hané</p> | <p>Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs</p> | <p>Ident. kód: BPR00015 Strana: 2 z 16 Počet příloh: 0 Verze: V001 Výtisk číslo:</p> |
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2. PRODUCTION INFORMATION

Summary information scheme on batch specific production data including data of different production stages, production sites and identification numbers.

Product name:

Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs.

Product batch number: 05 53 22

| Component and ID No. | Site(s) of manufacture | Date of manufacture |
|--|------------------------|---------------------|
| DHPPi component 04 60 21 B | | |
| Canine distemper virus 04/2014/CDV | Bioveta, a.s. | 27.10.2014 |
| Virus laryngotracheitidis contagiosae canis 73/2014/CAV-2 | Bioveta, a.s. | 11.2.2014 |
| Parvovirus enteritidis canis, strain 2b 01/2014/CPV-2b | Bioveta, a.s. | 11.4.2014 |
| Virus parainfluenzis canis 73/2014/CPIV-2 | Bioveta, a.s. | 20.5.2014 |
| Lyophilisation medium 88 58 21 | Bioveta, a.s. | 22.8.2014 |

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| Bioveta, a.s. Ivanovice na Hané | Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs | Ident. kód: | BPR00015 |
| | | Strana: | 3 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.1 STARTING MATERIAL

2.1.1 DHPPi COMPONENT

2.1.1.1 Canine distemper virus (CDV) part

2.1.1.1.1 Virus seed lots

| | |
|-----------------------------|--------------------------------------|
| Master seed material | Batch number |
| MSV Bio-11/A: CDV | 4 th passage of 14.8.2007 |
| | Date of last testing |
| | 20.9.2007 |

| | |
|------------------------------|--------------------------------------|
| Working seed material | Batch number |
| WSV Bio-11/A: CDV | 2 th passage of 14.3.2014 |
| | Date of last testing |
| | 14.3.2014 |

2.1.1.1.2 Cell seed lots

| | |
|-----------------------------|---|
| Master seed material | Batch number |
| MCS Bio-107: VERO | 139 th passage of 25.10.2001 |
| | Date of last testing |
| | 8.8.2006 |

| | |
|------------------------------|---------------------------------------|
| Working seed material | Batch number |
| WCS Bio-107: VERO | 145 th passage of 8.2.2013 |
| | Date of last testing |
| | 25.3.2014 |

2.1.1.1.3 Other materials of animal origin

| | |
|-----------------------------------|---------------------|
| Material | Batch number |
| Foetal bovine serum (Category EU) | A 10312-2859 |
| Trypsin | 26 57 21 |

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|------------------------------------|--|---------------|----------|
| Bioveta, a.s. Ivanovice na Hané | Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs | Ident. kód: | BPR00015 |
| | | Strana: | 4 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.1.1.2 Canine adenovirus-2 (CAV-2) part

2.1.1.2.1 Virus seed lots

| Master seed material | Batch number |
|----------------------|---------------------------------------|
| MSV Bio-13: CAV-2 | 4 th passage of 26.10.1994 |
| | Date of last testing |
| | 23.10.2008 |

| Working seed material | Batch number |
|-----------------------|---------------------------------------|
| WSV Bio-13: CAV-2 | 6 th passage of 23.10.2012 |
| | Date of last testing |
| | 9.11.2012 |

2.1.1.2.2 Cell seed lots

| Master seed material | Batch number |
|----------------------|---------------------------------------|
| MCS Bio-108: MDCK | 69 th passage of 29.7.2002 |
| | Date of last testing |
| | 28.3.2008 |

| Working seed material | Batch number |
|-----------------------|--------------------------------------|
| WCS Bio-108: MDCK | 75 th passage of 8.3.2013 |
| | Date of last testing |
| | 26.3.2014 |

2.1.1.2.3 Other materials of animal origin

| Material | Batch number |
|-----------------------------------|----------------|
| Foetal bovine serum (Category EU) | A 18312 – 1178 |
| Trypsin | 126220 |

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| | | Strana: | 5 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.1.1.3 Canine parvovirus (CPV-2b) part

2.1.1.3.1 Virus seed lots

| | |
|-----------------------------|---------------------------------------|
| Master seed material | Batch number |
| MSV Bio-12/B: CPV-2b (MDCK) | 45 th passage of 10.6.2009 |
| | Date of last testing |
| | 11.9.2009 |

| | |
|------------------------------|--------------------------------------|
| Working seed material | Batch number |
| WCS Bio-12/B: CPV-2b (MDCK) | 1 st passage of 11.6.2014 |
| | Date of last testing |
| | 5.8.2014 |

2.1.1.3.2 Cell seed lots

| | |
|-----------------------------|---------------------------------------|
| Master seed material | Batch number |
| MCS Bio-108: MDCK | 69 th passage of 29.7.2002 |
| | Date of last testing |
| | 28.3.2008 |

| | |
|------------------------------|--------------------------------------|
| Working seed material | Batch number |
| WCS Bio-108: MDCK | 75 th passage of 8.3.2013 |
| | Date of last testing |
| | 26.3.2014 |

2.1.1.3.3 Other materials of animal origin

| | |
|-----------------------------------|---------------------|
| Material | Batch number |
| Foetal bovine serum (Category EU) | A10312-2859 |
| Trypsin | 26 57 21 |

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| | | Strana: | 6 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.1.1.4 Canine parainfluenza-2 virus (CPIV-2) part

2.1.1.4.1 Virus seed lots

| Master seed material | Batch number |
|----------------------|-------------------------------------|
| MSV Bio-15: CPIV-2 | 7 th passage of 4.3.1997 |
| | Date of last testing |
| | 13.10.2009 |

| Working seed material | Batch number |
|-----------------------|--------------------------------------|
| WSV Bio-15: CPIV-2 | 9 th passage of 25.2.2013 |
| | Date of last testing |
| | 27.8.2013 |

2.1.1.4.2 Cell seed lots

| Master seed material | Batch number |
|----------------------|---|
| MCS Bio-107: VERO | 139 th passage of 25.10.2001 |
| | Date of last testing |
| | 8.8.2006 |

| Working seed material | Batch number |
|-----------------------|---------------------------------------|
| WCS Bio-107: VERO | 145 th passage of 8.2.2013 |
| | Date of last testing |
| | 25.3.2014 |

2.1.1.4.3 Other materials of animal origin

| Material | Batch number |
|-----------------------------------|------------------------------|
| Foetal bovine serum (Category EU) | A10112-2859 |
| Trypsin | 17 52 21, 18 54 21, 19 54 21 |

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| | | Strana: 7 z 16 |
| | | Počet příloh: 0 |
| | | Verze: V001 |
| | | Výtisk číslo: |

2.2 INTERMEDIATE STAGES OF PRODUCTION

2.2.1 DHPPI COMPONENT

2.2.1.1 Canine distemper virus part

Production of canine distemper virus, Bio-11/A: CDV, batch 04/2014/CDV

| Production step | Start | End | Material | Volume | Other relevant data |
|-----------------|------------|------------|---|------------------|--------------------------|
| Cell passaging | 16.10.2014 | 23.10.2014 | trypsin solution culture medium | - - | - |
| Infection | 23.10.2014 | 23.10.2014 | 2 th passage of 14.3.2014 maintaining medium | 40 ml c. 15 l | - |
| Harvest | 27.10.2014 | 27.10.2014 | 04/2014/CDV | c. 13.5 l | - |
| Storage | - | - | - | - | at temperature 2-8 °C |

2.2.1.2 Canine adenovirus-2 part

Production of canine adenovirus-2, Bio-13: CAV-2, batch 73/2014/CAV-2

| Production step | Start | End | Material | Volume | Other relevant data |
|-----------------|------------|------------|--|-------------------|----------------------------|
| Cell passaging | 3.1.2014 | 6.2.2014 | trypsin solution culture medium | - - | - |
| Infection | 6.2.2014 | 6.2.2014 | 6 th passage of 23.10.2012 maintaining medium | 200 ml c. 40 l | - |
| Harvest | 11.2.2014 | 11.2.2014 | 73/2014/CAV-2 | c. 38.2 l | - |
| Storage | 11.2.2014 | 24.10.2014 | - | - | at temperature < -25 °C |
| Storage | 24.10.2014 | 27.10.2014 | - | - | at temperature 2-8 °C |

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| | | Strana: | 8 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.2.1.3 Canine parvovirus part

Production of canine parvovirus, Bio-12/B: CPV-2b (MDCK), batch 01/2014/CPV-2b

| Production step | Start | End | Material | Volume | Other relevant data |
|--|------------|------------|--|---------------------|-------------------------------|
| Cell passaging | 21.3.2014 | 27.3.2014 | trypsin solution culture medium | - - | - |
| Infection | 27.3.2014 | 27.3.2014 | 45 th passage of 10.6.2009 culture medium | 3.2 ml c. 0.75 l | - |
| Subpassage | 31.3.2014 | - | trypsin solution culture medium | 3.15 l | 1 st |
| Subpassage | 3.4.2014 | - | trypsin solution culture medium | 9.75 l | 2 nd |
| Subpassage | 7.4.2014 | - | trypsin solution culture medium | 36 l | 3 rd |
| Subpassage | - | - | trypsin solution culture medium | - | 4 th |
| Exchanging of the cultivation medium | 8.4.2014 | 8.4.2014 | maintaining medium | c. 36 l | |
| Harvest | 11.4.2014 | 11.4.2014 | 01/2014/CPV-2b | c. 36 l | - |
| Storage | 11.4.2014 | 24.10.2014 | - | - | at temperature < -25 °C |
| Storage | 24.10.2014 | 27.10.2014 | - | - | at temperature 2-8 °C |

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Production of canine parainfluenza-2 virus, Bio-15: CPIV-2, batch 73/2014/CPIV-2

| Production step | Start | End | Material | Volume | Other relevant data |
|-----------------|------------|------------|--|-----------------------|-----------------------------------|
| Cell passaging | 9.4.2014 | 16.5.2014 | trypsin solution culture medium | - - | - |
| Infection | 16.5.2014 | 16.5.2014 | 9 th passage of 25.2.2013 maintaining medium | 400 ml c. 40 l | - |
| Harvest | 20.5.2014 | 20.5.2014 | 73/2014/CPIV-2 | c. 38 l | |
| Storage | 20.5.2014 | 24.10.2014 | - | - | at temperature < -50 °C |
| Storage | 24.10.2014 | 27.10.2014 | - | - | at temperature 2-8 °C |

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2.3 CREATION OF THE FINAL PRODUCT

2.3.1 BLENDING AND VACCINE COMPOSITION

2.3.1.1 BLENDING

2.3.1.1.1 DHPPi component

| Component | Start date | End date | Bulk number | Total volume |
|------------------------------|------------|------------|----------------|--------------|
| Canine distemper virus | 27.10.2014 | 27.10.2014 | 04/2014/CDV | 13.5 l |
| Canine adenovirus-2 | 27.10.2014 | 27.10.2014 | 73/2014/CAV-2 | 5.4 l |
| Canine parvovirus-2b | 27.10.2014 | 27.10.2014 | 01/2014/CPV-2b | 8.1 l |
| Canine parainfluenza-2 virus | 27.10.2014 | 27.10.2014 | 73/2014/CPIV-2 | 10.8 l |
| Lyophilisation medium | 27.10.2014 | 27.10.2014 | 88 58 21 | 16.2 l |
| Storage 2-8°C | 27.10.2014 | 3.11.2014 | 24 60 21 | 54 l |

2.3.1.2 VACCINE COMPOSITION

2.3.1.2.1 DHPPi component

| Component | Batch no. | Final volume | Target ratio |
|------------------------------|----------------|--------------|--------------|
| Canine distemper virus | 04/2014/CDV | 13.5 l | 70% |
| Canine adenovirus-2 | 73/2014/CAV-2 | 5.4 l | |
| Canine parvovirus | 01/2014/CPV-2b | 8.1 l | |
| Canine parainfluenza-2 virus | 73/2014/CPIV-2 | 10.8 l | |
| Lyophilisation medium | 88 58 21 | 16.2 l | 30% |

2.3.2 FILLING

2.3.2.1 DHPPi component

| Start 3.11.2014 | | End 3.11.2014 | |
|------------------------------|--------------|------------------|--------------------|
| Product-subbatch number | Filling date | Filled container | Volume filled (ml) |
| DHPPi component 04 60 21B | 3.11.2014 | 15 379 pcs | 1.0 ml |

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2.3.2.2 WFI component

| | | | |
|--------------------------------|-------------------------|-------------------------|---------------------------|
| Start 11.2.2015 | End 11.2.2015 | | |
| Product-subbatch number | Filling date | Filled container | Volume filled (ml) |
| WFI component 82 52 22 B | 11.2.2015 | 97 002 pcs | 1.2 ml |

2.3.3 LYOPHILISATION

| Final batch number | Start date | End date | Number of containers |
|-------------------------------|-------------------|-----------------|-----------------------------|
| DHPPi component 04 60 21 B | 3.11.2014 | 5.11.2014 | 14 725 pcs |

| | | | |
|------------------------------------|--|---------------|----------|
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| | | Strana: | 12 z 16 |
| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

2.4 IN PROCESS CONTROL

2.4.1 DHPPi component

2.4.1.1 In process controls on live viral suspension

2.4.1.1.1. Canine distemper virus, Bio-11/A: CDV, Batch 04/2014/CDV

| Test | Start | End | Result | Thresholds | Conclusion |
|----------------|------------|------------|--|---|------------|
| Titre | 27.10.2014 | 3.11.2014 | 10 ^{6.6} TCID ₅₀ /ml | min. 10 ^{5.6} TCID ₅₀ /ml | satisfy |
| Mycoplasma | 10.11.2014 | 10.11.2014 | complies | Free from mycoplasma | satisfy |
| Sterility test | 27.10.2014 | 10.11.2014 | Sterile | must be sterile | satisfy |

2.4.1.1.2. Canine adenovirus-2, Bio-13: CAV-2, Batch 73/2014/CAV-2

| Test | Start | End | Result | Thresholds | Conclusion |
|----------------|-----------|-----------|--|---|------------|
| Titre | 11.2.2014 | 18.2.2014 | 10 ^{6.3} TCID ₅₀ /ml | min. 10 ^{5.3} TCID ₅₀ /ml | satisfy |
| Mycoplasma | 25.2.2014 | 25.2.2014 | complies | Free from mycoplasma | satisfy |
| Sterility test | 11.2.2014 | 25.2.2014 | Sterile | must be sterile | satisfy |

2.4.1.1.3. Canine parvovirus, Bio-12/B: CPV-2b (MDCK), Batch 01/2014/CPV-2b

| Test | Start | End | Result | Thresholds | Conclusion |
|----------------|-----------|-----------|--|---|------------|
| Titre | 14.4.2014 | 21.4.2014 | 10 ^{6.1} TCID ₅₀ /ml | min. 10 ^{6.1} TCID ₅₀ /ml | satisfy |
| Identity | 25.4.2014 | 25.4.2014 | complies | CPV type must be CPV 2a, b, c group | satisfy |
| Mycoplasma | 25.4.2014 | 25.4.2014 | complies | Free from mycoplasma | satisfy |
| Sterility test | 11.4.2014 | 25.4.2014 | Sterile | must be sterile | satisfy |

2.4.1.1.3. Canine parainfluenza-2 virus, Bio-15: CPIV-2, Batch 73/2014/CPIV-2

| Test | Start | End | Result | Thresholds | Conclusion |
|----------------|-----------|-----------|--|---|------------|
| Titre | 21.5.2014 | 28.5.2014 | 10 ^{7.1} TCID ₅₀ /ml | min. 10 ^{6.3} TCID ₅₀ /ml | satisfy |
| Mycoplasma | 3.6.2014 | 3.6.2014 | complies | Free from mycoplasma | satisfy |
| Sterility test | 20.5.2014 | 3.6.2014 | Sterile | must be sterile | satisfy |

2.4.1.2 IN-PROCESS CONTROL ON DHPPi BULK VACCINE AFTER BLENDING

| Test | Start | End | Result | Thresholds | Conclusion |
|----------------|------------|------------|---------|-----------------|------------|
| pH | 3.11.2014 | 3.11.2014 | 7.17 | 7.0 – 7.3 | Satisfy |
| Sterility test | 27.10.2014 | 10.11.2014 | Sterile | Must be sterile | Satisfy |

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| | | Počet příloh: | 0 |
| | | Verze: | V001 |
| | | Výtisk číslo: | |

3. FINAL PRODUCT TESTING

| Test | Start | End | Result | Thresholds | Conclusion |
|---|------------|------------|-----------------------------|---|------------|
| FREEZE-DRIED FRACTION (DHPPI) 04 60 21 B | | | | | |
| Appearance | 12.11.2014 | 12.11.2014 | complies | Spongy matter, white colour. | satisfy |
| CDV identity | 14.11.2014 | 21.11.2014 | 4.1 | Neutralisation index $\geq 2 \log_{10}$ and/or specific immunofluorescence has to be seen in the cell culture infected with CDV | satisfy |
| CPV identity | 25.11.2014 | 25.11.2014 | complies | CPV type must be CPV 2a, b, c group | satisfy |
| CAV-2 identity | 14.11.2014 | 21.11.2014 | 4.8 | Neutralisation index $\geq 2 \log_{10}$ and/or specific immunofluorescence has to be seen in the cell culture infected with CAV-2 | satisfy |
| CPIV-2 identity | 14.11.2014 | 21.11.2014 | 4.3 | Neutralisation index $\geq 2 \log_{10}$ and/or specific immunofluorescence has to be seen in the cell culture infected with CPIV | satisfy |
| CDV titre | 14.11.2014 | 21.11.2014 | $10^{4.1} \text{TCID}_{50}$ | min. $10^{4.0} \text{TCID}_{50}$ max. $10^{5.1} \text{TCID}_{50}$ | satisfy |
| CPV titre | 14.11.2014 | 21.11.2014 | $10^{6.6} \text{TCID}_{50}$ | min. $10^{5.1} \text{TCID}_{50}$ max. $10^{6.6} \text{TCID}_{50}$ | satisfy |
| CAV-2 titre | 14.11.2014 | 21.11.2014 | $10^{4.8} \text{TCID}_{50}$ | min. $10^{4.2} \text{TCID}_{50}$ max. $10^{5.3} \text{TCID}_{50}$ | satisfy |
| CPIV-2 titre | 14.11.2014 | 21.11.2014 | $10^{4.3} \text{TCID}_{50}$ | min. $10^{3.6} \text{TCID}_{50}$ max. $10^{5.1} \text{TCID}_{50}$ | satisfy |
| Mycoplasma | 25.11.2014 | 25.11.2014 | complies | Free from mycoplasma. | satisfy |

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| | | Počet příloh: | 0 |
| | | Verze: | V001 |
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| Test | Start | End | Result | Thresholds | Conclusion |
|---------------------------------|------------|------------|----------|---|------------|
| Extraneous agents | 14.11.2014 | 5.12.2014 | complies | Free from extraneous agents. | satisfy |
| Residual humidity | 12.11.2014 | 12.11.2014 | 0.58 % | 0.5 to 3 % | satisfy |
| Sterility freeze-dried fraction | 10.11.2014 | 24.11.2014 | complies | Must be sterile. | satisfy |
| Vacuum | 12.11.2014 | 12.11.2014 | complies | Residual pressure must be lower than 2.66 Pa. | satisfy |

LIQUID FRACTION (WFI) 82 52 22 B

| Test | Start | End | Result | Thresholds | Conclusion |
|--|-----------|-----------|----------------------------|--|------------|
| Appearance | 4.3.2015 | 4.3.2015 | complies | Clear colourless liquid without taste and smell. | satisfy |
| Extractable volume | 4.3.2015 | 4.3.2015 | 1.08 ml | Minimum 1 ml | satisfy |
| Air Tightness | 4.3.2015 | 4.3.2015 | complies | The glass vial must be hermetically closed. | satisfy |
| Acidity or alkalinity | 4.3.2015 | 4.3.2015 | complies | Must comply with Ph. Eur. | satisfy |
| Conductivity | 4.3.2015 | 4.3.2015 | 24.5 $\mu\text{S.cm}^{-1}$ | Maximum 25 $\mu\text{S.cm}^{-1}$. | satisfy |
| Oxidisable substances | 4.3.2015 | 4.3.2015 | complies | Must comply with Ph. Eur. | satisfy |
| Chlorides | 4.3.2015 | 4.3.2015 | < 0.5ppm | Maximum 0.5 ppm. | satisfy |
| Nitrates | 4.3.2015 | 4.3.2015 | < 0.2ppm | Maximum 0.2 ppm. | satisfy |
| Sulfates | 4.3.2015 | 4.3.2015 | complies | Must comply with Ph. Eur. | satisfy |
| Ammonium | 4.3.2015 | 4.3.2015 | < 0.6ppm | Maximum 0.6 ppm. | satisfy |
| Calcium and magnesium | 4.3.2015 | 4.3.2015 | complies | Must comply with Ph. Eur. | satisfy |
| Residue on evaporation | 4.3.2015 | 4.3.2015 | < 0.004 % | Maximum 4 mg (0.004%). | satisfy |
| Bacterial endotoxins (Ph. Eur. 2.6.14) | 16.2.2015 | 16.2.2015 | <0.25 IU/ml | Less than 0.25 IU/ml. | satisfy |
| Sterility (Ph. Eur. 2.6.1) | 17.2.2015 | 3.3.2015 | complies | The preparation must be sterile. | satisfy |

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RECONSTITUTED VACCINE (batch no.05 53 22)

| Test | Start | End | Result | Thresholds | Conclusion |
|------------|-----------|-----------|----------|---|------------|
| Appearance | 30.3.2015 | 30.3.2015 | complies | Clear whitish to yellowish colour with light opalescence. | satisfy |
| pH | 30.3.2015 | 30.3.2015 | 7.90 | 6.5 – 8.0 | satisfy |

| | | |
|------------------------------------|--|--|
| Bioveta, a.s. Ivanovice na Hané | Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs | Ident. kód: BPR00015 Strana: 16 z 16 Počet příloh: 0 Verze: V001 Výtisk číslo: |
|------------------------------------|--|--|

4. CERTIFICATION BY THE MANUFACTURER

Certification by qualified person taking the overall responsibility for production and control of the product: **Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs** batch N° 05 53 22

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local regulatory Authority and with the specifications on the Marketing Authorization of the importing country. The batch processing, packing and analysis records were reviewed and found to be in compliance with GMP.

NAME: Mgr. Hana Nezvalová

FUNCTION: Quality Control Head

DATE: 4.1.2016

SIGNATURE: 