

## CERTIFICATE OF ANALYSIS

Product: **Biocan Novel Puppy, liofilizat si solvent pentru suspensie injectabilă**

Batch No.: **14 61 26 A**

Expiry: **03.11.2021**

Date of production: **04.11.2019**

### Results of analysis:

| Tests                                  | Release limits                                                                                              | Shelf-life limits                                                       | Results                       |
|----------------------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------|
| Freeze - dried fraction                |                                                                                                             |                                                                         |                               |
| Appearance                             | Lyophilized vaccine is spongy consistency, white colour.                                                    |                                                                         | complies                      |
| Sterility                              | Vaccine must be sterile.                                                                                    |                                                                         | sterile                       |
| Mycoplasma                             | Vaccine must be free from <i>mycoplasma</i> .                                                               |                                                                         | complies                      |
| Extraneous viruses                     | Free from extraneous agents.                                                                                |                                                                         | complies                      |
| Virus titre                            | Function: To determine the virus titre (potency) of each CDV and CPV-2b antigen in the finished product.    |                                                                         | complies                      |
| CDV                                    | min. $10^{4.7}$ TCID <sub>50</sub> - max. $10^{5.5}$ TCID <sub>50</sub>                                     | min. $10^{4.1}$ TCID <sub>50</sub> - max. $10^{5.5}$ TCID <sub>50</sub> | $10^{4.8}$ TCID <sub>50</sub> |
| CPV-2b                                 | min. $10^{6.0}$ TCID <sub>50</sub> - max. $10^{7.0}$ TCID <sub>50</sub>                                     | min. $10^{5.5}$ TCID <sub>50</sub> - max. $10^{7.0}$ TCID <sub>50</sub> | $10^{6.6}$ TCID <sub>50</sub> |
| Identity                               | Function: The test is performed to confirm presence of each CDV and CPV-2b antigen in the finished product. |                                                                         | complies                      |
| CDV                                    | Neutralization index has to be equal or higher than 2 log10, NI ≥ 2                                         |                                                                         | 4.8                           |
| CPV-2b                                 | The CPV type must be CPV 2a, b, c group.                                                                    |                                                                         | complies                      |
| Residual humidity                      | max. 3 %                                                                                                    |                                                                         | 2.7 %                         |
| Vacuum                                 | The vials sealed under vacuum must be evacuated to a residual pressure lower than 2.66 Pa.                  |                                                                         | complies                      |
| Water for injection - liquid fraction  |                                                                                                             |                                                                         |                               |
| Appearance                             | Clear colourless liquid without smell.                                                                      |                                                                         | complies                      |
| Bacterial endotoxins (Ph. Eur. 2.6.14) | Less than 0.25 IU/ml.                                                                                       |                                                                         | <0.01 IU/ml                   |
| Sterility (Ph. Eur. 2.6.1)             | The preparation must be sterile.                                                                            |                                                                         | sterile                       |
| Extractable volume (Ph.Eur. 2.9.17)    | Minimum 1 ml.                                                                                               |                                                                         | 1 ml                          |
| Air tightness                          | The vial must be hermetically closed.                                                                       |                                                                         | complies                      |
| Acidity or alkalinity                  | Must comply with Ph. Eur.                                                                                   |                                                                         | complies                      |
| Conductivity                           | Maximum 25 µS.cm-1                                                                                          |                                                                         | 8.0 µS.cm-1                   |
| Oxidisable substances                  | Must comply with Ph. Eur.                                                                                   |                                                                         | complies                      |
| Chlorides                              | Maximum 0.5 ppm                                                                                             |                                                                         | <0.5 ppm                      |
| Nitrates                               | Maximum 0.2 ppm                                                                                             |                                                                         | <0.2 ppm                      |
| Sulfates                               | Must comply with Ph. Eur.                                                                                   |                                                                         | complies                      |
| Ammonium                               | Maximum 0.6 ppm                                                                                             |                                                                         | <0.6 ppm                      |
| Heavy metals                           | Maximum 0.1 ppm                                                                                             |                                                                         | <0.1 ppm                      |
| Calcium and magnesium                  | Must comply with Ph. Eur.                                                                                   |                                                                         | complies                      |
| Residue on evaporation                 | Maximum 4 mg (0.004 %)                                                                                      |                                                                         | 3 mg                          |
| Reconstituted Vaccine                  |                                                                                                             |                                                                         |                               |
| Appearance                             | Clear, colourless to yellowish liquid with slight opalescence.                                              |                                                                         | complies                      |
| pH                                     | 6.5 – 8.0                                                                                                   |                                                                         | 7.3                           |

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 456.



15/06/2020  
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HEAD of QC, QP