



## CERTIFICATE OF ANALYSIS

Product: **Biocan DHPPi**

Batch No.: **985128A**

Expiry: **21.1.2023**

Date of production: **22.1.2021**

### Results of analysis:

| Tests                                               | Release limits                                                                                                                                                          | Shelf-life limits | Results                       |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------|
| Appearance                                          | Lyophilised vaccine is spongy matter, white to cream or pinkish colour. After dissolving in diluent the vaccine is pink-red or yellowish colour with light opalescence. |                   | conforms                      |
| pH                                                  | 6.5 – 8.0                                                                                                                                                               |                   | 7.5                           |
| Sterility                                           | Vaccine must be sterile.                                                                                                                                                |                   | sterile                       |
| Mycoplasma                                          | Vaccine should not contain mycoplasma.                                                                                                                                  |                   | conforms                      |
| Extraneous viruses                                  | Vaccine should not contain any extraneous viruses.                                                                                                                      |                   | conforms                      |
| Residual humidity                                   | Max. 3%.                                                                                                                                                                |                   | 1.7 %                         |
| Virus titre:                                        |                                                                                                                                                                         |                   |                               |
| CDV - Virus febris contagiosae canis                | min. $10^{3.0}$ TCID <sub>50</sub> , max. $10^{4.5}$ TCID <sub>50</sub>                                                                                                 |                   | $10^{3.3}$ TCID <sub>50</sub> |
| CAV-2 - Virus laryngotracheitidis contagiosae canis | min. $10^{3.5}$ TCID <sub>50</sub> , max. $10^{4.5}$ TCID <sub>50</sub>                                                                                                 |                   | $10^{4.3}$ TCID <sub>50</sub> |
| CPV – Parvovirus enteritidis canis                  | min. $10^{4.5}$ TCID <sub>50</sub> , max. $10^{5.5}$ TCID <sub>50</sub>                                                                                                 |                   | $10^{5.1}$ TCID <sub>50</sub> |
| CPiV-2 - Virus parainfluenzae canis                 | min. $10^{3.0}$ TCID <sub>50</sub> , max. $10^{4.2}$ TCID <sub>50</sub>                                                                                                 |                   | $10^{3.3}$ TCID <sub>50</sub> |
| Virus identity                                      | CDV: Neutralisation index $\geq 2$ .                                                                                                                                    |                   | 3.3                           |
|                                                     | CAV-2: Neutralisation index $\geq 2$ .                                                                                                                                  |                   | 4.3                           |
|                                                     | CPV: Neutralisation index $\geq 2$ .                                                                                                                                    |                   | 3.0                           |
|                                                     | CPiV-2: Neutralisation index $\geq 2$ .                                                                                                                                 |                   | 3.3                           |

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. 141.



.....23/06/2021  
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HEAD of QC, QP