



## CERTIFICATE OF ANALYSIS

Product: **Biocan DP, liofilizat pentru soluție injectabilă și diluant**

Batch No.: **295728A**

Expiry: **6.7.2023**

Date of production: **7.7.2021**

### Results of analysis:

| Tests                                | Specification                                                                                                                                                                      | Results                       |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| Appearance                           | Lyophilised vaccine is spongy matter, white to cream or pinkish colour. After dissolving in diluent the vaccine is pink-red to yellowish or whitish colour with light opalescence. | conforms                      |
| Mycoplasma                           | Vaccine should not contain mycoplasma.                                                                                                                                             | conforms                      |
| Extraneous viruses                   | Vaccine should not contain any extraneous viruses.                                                                                                                                 | conforms                      |
| Residual humidity                    | Lyophilised product doesn't contain more than 3% residual humidity.                                                                                                                | 1.5 %                         |
| Airtightness                         | The vials should be hermetically sealed.                                                                                                                                           | conforms                      |
| Sterility                            | Vaccine should be sterile.                                                                                                                                                         | sterile                       |
| pH                                   | 6.5 – 8.0                                                                                                                                                                          | 7.6                           |
| Virus titre:                         |                                                                                                                                                                                    |                               |
| CDV – Virus febris contagiosae canis | min. $10^{3.0}$ TCID <sub>50</sub> , max. $10^{4.8}$ TCID <sub>50</sub>                                                                                                            | $10^{3.8}$ TCID <sub>50</sub> |
| CPV – Parvovirus enteritidis canis   | min. $10^{4.5}$ TCID <sub>50</sub> , max. $10^{6.0}$ TCID <sub>50</sub>                                                                                                            | $10^{5.8}$ TCID <sub>50</sub> |
| Virus identity:                      |                                                                                                                                                                                    |                               |
| CDV                                  | Neutralisation index $\geq 2$ .                                                                                                                                                    | 3.8                           |
| CPV                                  | Neutralisation index $\geq 2$ .                                                                                                                                                    | 3.5                           |
| Potency                              | Vaccine should be efficient.                                                                                                                                                       | conforms                      |

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. 140, spec.02.



*Hana*  
.....6/10/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP