

## CERTIFICATE OF ANALYSIS

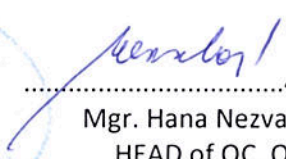
Product: **Biocan P inj. sicc. ad-ne. vet.**Batch No.: **345129A**Expiry: **01/2024**Date of production: **31.1.2022**

## Results of analysis:

| Tests              | Release limits                                                                                                                                                  | Shelf-life limits | Results                       |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------------------|
| Appearance         | Lyophilised vaccine is spongy matter, cream and pinkish colour. After dissolving in diluent the vaccine is pink-red or yellowish 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.                                                                                             |                   | 0.9 %                         |
| Airtightness       | The vials should be hermetically sealed.                                                                                                                        |                   | conforms                      |
| Sterility          | Vaccine should be sterile.                                                                                                                                      |                   | sterile                       |
| pH                 | 6.5 – 8.0                                                                                                                                                       |                   | 7.7                           |
| Virus titre        | CPV – Parvovirus enteritidis canis<br>min. $10^{5.0}$ TCID <sub>50</sub> , max. $10^{6.2}$ TCID <sub>50</sub>                                                   |                   | $10^{6.1}$ TCID <sub>50</sub> |
| Virus identity     | CPV<br>Neutralisation index $\geq 2$ .                                                                                                                          |                   | 4.1                           |
| Efficacy           | 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. 134,V002.



  
.....4/4/2022  
Mgr. Hana Nezvalová  
HEAD of QC, QP