



## CERTIFICATE OF ANALYSIS

Product: **Biocan L inj. ad us. vet.**

Batch No.: **586127A**

Expiry: **9.11.2022**

Date of production: **10.11.2020**

### Results of analysis:

| Tests                          | Specification                                                                                                                                                                          | Results                |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Appearance                     | Whitish to pink liquid, after standing is separated in white sediment and almost clear supernatant.                                                                                    | conforms               |
| Extractable volume             | Minimum 1.0 ml.                                                                                                                                                                        | 1.1 ml                 |
| Sterility                      | Vaccine must be sterile.                                                                                                                                                               | sterile                |
| Efficacy and identity          | Vaccine must be efficient. Geometric average of antibody ARL titre must be min. 1:32 after vaccination and revaccination for L. icterohaemorrhagiae, L. canicola and L. grippotyphosa. | L. icterohaemorrhagiae |
|                                |                                                                                                                                                                                        | 1: 40                  |
|                                |                                                                                                                                                                                        | L. canicola            |
|                                |                                                                                                                                                                                        | 1: 51                  |
|                                |                                                                                                                                                                                        | L. grippotyphosa       |
|                                |                                                                                                                                                                                        | 1: 51                  |
| Inactivation                   | Vaccine must not contain live leptospira cultures.                                                                                                                                     | conforms               |
| Sera absence                   | Vaccine must not contain serum.                                                                                                                                                        | conforms               |
| Concentration of hydrogen ions | pH 7.0 – 8.2                                                                                                                                                                           | 7.6                    |
| Content of aluminium oxide     | 2.0 mg (1.8 – 2.2 mg/ml)                                                                                                                                                               | 1.95 mg/ml             |
| Airtightness                   | Vial must be hermetically closed.                                                                                                                                                      | 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. 249.



.....7/1/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP