

## CERTIFICATE OF ANALYSIS

Product: **BIOCAN LR**

Batch No.: **63 54 26 A**

Expiry: **10.04.2021**

Date of production: **11.04.2019**

### Results of analysis:

| Tests                                                                        | Specification                                                                                                                                                                          | Results                                |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Appearance                                                                   | Whitish liquid with easily shakeable sediment.                                                                                                                                         | conforms                               |
| Content of original package                                                  | min. 1 ml                                                                                                                                                                              | 1.1 ml                                 |
| Sterility                                                                    | Vaccine should be sterile.                                                                                                                                                             | sterile                                |
| Inactivation (in-process control) – L component                              | The vaccine should not contain live leptospira cultures.                                                                                                                               | conforms                               |
| Inactivation (in-process control) – R component                              | The vaccine should not contain live rabies virus.                                                                                                                                      | conforms                               |
| Serum absence (in-process control)                                           | The vaccine should not contain serum.                                                                                                                                                  | conforms                               |
| pH                                                                           | 6.5 – 8.0                                                                                                                                                                              | 7.8                                    |
| Content of aluminium hydroxide (measured as Al <sub>2</sub> O <sub>3</sub> ) | Aluminium oxide content – 2 mg/ml (1.8 – 2.2 mg/ml).                                                                                                                                   | 2.00 mg/ml                             |
| Airtightness                                                                 | Vial should be hermetically closed.                                                                                                                                                    | conforms                               |
| <b>Antigen titre:</b>                                                        |                                                                                                                                                                                        |                                        |
| Virus rabiei inact.                                                          | min. 2 IU, max. 4 IU                                                                                                                                                                   | 3.7 IU                                 |
| L.icterohaemorrhagiae inact                                                  | min. 1x10 <sup>7.0</sup> TCID <sub>50</sub> , max. 1x10 <sup>9.0</sup> TCID <sub>50</sub>                                                                                              | 6x10 <sup>7.0</sup> TCID <sub>50</sub> |
| L. canicola inact.                                                           | min. 1x10 <sup>7.0</sup> TCID <sub>50</sub> , max. 1x10 <sup>9.0</sup> TCID <sub>50</sub>                                                                                              | 6x10 <sup>7.0</sup> TCID <sub>50</sub> |
| L. grippotyphosa inact.                                                      | min. 1x10 <sup>7.0</sup> TCID <sub>50</sub> , max. 1x10 <sup>9.0</sup> TCID <sub>50</sub>                                                                                              | 6x10 <sup>7.0</sup> TCID <sub>50</sub> |
| <b>Efficacy and identity:</b>                                                |                                                                                                                                                                                        |                                        |
| L component:                                                                 | 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: 32           |
|                                                                              |                                                                                                                                                                                        | L. canicola 1: 51                      |
|                                                                              |                                                                                                                                                                                        | L. grippotyphosa 1: 64                 |
| R component:                                                                 | The rabies component stimulates the production of specific neutralizing antibodies. Vaccine should contain min. 2 IU and max. 4 IU (vaccination dose).                                 | 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. 150, spec.02.



.....24/06/2019  
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HEAD of QC,QP