

## CERTIFICATE OF ANALYSIS

Product: **ROKOVAC NEO, emulsie injectabilă**

Batch No.: **76 52 27 B**

Expiry: **20.02.2022**

Date of production: **21.02.2020**

**Results of analysis:**

| Tests                                                                                                                                                                               | Release limits                                                                         | Shelf-life limits | Results                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------|--------------------------------|
| Appearance                                                                                                                                                                          | Milky white to light pink oily liquid containing a sediment that can be easily shaken. |                   | conforms                       |
| Content of original package                                                                                                                                                         | min. 10 ml, 20 ml, 50 ml, 100 ml, 250 ml                                               |                   | 51 ml                          |
| Sterility                                                                                                                                                                           | Vaccine must be sterile.                                                               |                   | sterile                        |
| Efficacy                                                                                                                                                                            | Vaccine must comply the test for efficacy.                                             |                   | conforms                       |
|                                                                                                                                                                                     | <i>Rotavirus suis</i> inact. OSU 6                                                     | RP ≥ 1*           | 1.14                           |
|                                                                                                                                                                                     | <i>E. coli</i> inact. O101:K99 (F5)                                                    | RP ≥ 1*           | 1.07                           |
|                                                                                                                                                                                     | <i>E. coli</i> inact. O147:K88 (F4)                                                    | RP ≥ 1*           | 1.12                           |
|                                                                                                                                                                                     | <i>E. coli</i> inact. O149:K88 (F4)                                                    | RP ≥ 1*           | 1.12                           |
|                                                                                                                                                                                     | <i>E. coli</i> inact. K85:987P (F6)                                                    | RP ≥ 1*           | 1.10                           |
|                                                                                                                                                                                     | <i>E. coli</i> inact. O101:K99:F41 (F5, F41)                                           | RP ≥ 1*           | 1.23                           |
| * Relative potency (determined by ELISA method) in comparison with reference serum obtained from mice vaccination with batch, which complied with challenge test on target species. |                                                                                        |                   |                                |
| Identity                                                                                                                                                                            | Vaccine must comply the test for identity.                                             |                   | conforms                       |
| Formaldehyde content                                                                                                                                                                | max. 0.19 %                                                                            |                   | 0.01 %                         |
| pH                                                                                                                                                                                  | 6.0 – 7.8                                                                              |                   | 7.3                            |
| Thiomersal content                                                                                                                                                                  | 0.1 mg/ml (0.085 – 0.115 mg/ml)                                                        |                   | 0.091 mg/ml                    |
| Air tightness                                                                                                                                                                       | The vials must be hermetically sealed.                                                 |                   | conforms                       |
| Inactivation test <sup>1</sup>                                                                                                                                                      | The vaccine must contain inactivated antigens.                                         |                   | conforms                       |
| Bacterial endotoxins <sup>1</sup>                                                                                                                                                   | max. 1 × 10 <sup>6</sup> / 1 vaccination dose                                          |                   | 9.70x10 <sup>4</sup> / 1 v. d. |
| Viscosity                                                                                                                                                                           | 1.0 - 4.0 mPa.s                                                                        |                   | 3.4 mPa.s                      |

<sup>1</sup> test is made as in-process control

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. 191.



.....08/04/2020  
Mgr. Hana Nezvalová  
HEAD of QC, QP