

CERTIFICATE OF ANALYSIS

Product: **ROKOVAC NEO, emulsie injectabilă**

Batch No.: **976128B**

Expiry: **2.11.2023**

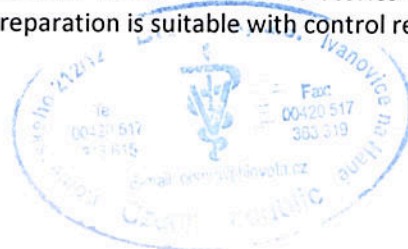
Date of production: **3.11.2021**

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		50 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*	1.20
	<i>E. coli</i> inact. O101:K99 (F5)	RP ≥ 1*	1.09
	<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*	1.18
* 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		7.2
Thiomersal content	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.097 mg/ml
Air tightness	The vials must be hermetically sealed.		conforms
Inactivation test ¹	The vaccine must contain inactivated antigens.		conforms
Bacterial endotoxins ¹	max. 1 × 10 ⁶ / 1 vaccination dose		1.30x10 ⁵ / 1 v. d.
Viscosity	1.0 - 4.0 mPa.s		3.4 mPa.s

¹ 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.



.....17/12/2021
Mgr. Hana Nezvalová
HEAD of QC, QP