



CERTIFICATE OF ANALYSIS

Product: BIOSUIS ROVACOL ενέσιμο γαλάκτωμα για χοίρους

Batch No.: 825927A

Expiry: 21.9.2022

Date of production: 22.9.2020

Results of analysis:

Tests	Release limits	Shelf-life limits		Results
Appearance	White up to faintly pink oily fluid 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
		before inactivation	final control	
	<i>Rotavirus suis</i> inact. OSU 6	min. 10 ^{5.0} TCID ₅₀ max. 10 ^{6.0} TCID ₅₀	RP ≥ 1*	1.44
	<i>E. coli</i> inact. F5 (O101:K99)	min.5.4x10 ^{9.0} CFU, max.5.4x10 ^{10.0} CFU	RP ≥ 1*	1.23
	<i>E. coli</i> inact. F4 (O147:K88, O149:K88)			1.16
	<i>E. coli</i> inact. F6 (K85:987P)			1.19
	<i>E. coli</i> inact. F5, F41 (O101:K99:F41)			1.14
* 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	The vaccine induces formation of specific antibodies.			conforms
Inactivation*	Vaccine must content inactivated antigen only.			conforms
Bacterial endotoxins*	Vaccine can contain max. 7×10 ⁵ IU/dose			8.90 ×10 ⁴ IU/dose
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)			0.090 mg/ml
Viscosity	1.0 – 4.0 mPa.s			4.0 mPa.s
Air tightness	The vials must be hermetically sealed.			conforms

* The test is performed on the intermediate product

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.

.....05/02/2021
Mgr. Hana Nezvalová
HEAD of QC, QP