

CERTIFICATE OF ANALYSIS

Product: **PARVOERY SIN**

Batch No.: **24 58 25 C**

Expiry: **13.02.2020**

Date of production: **14.08.2018**

Results of analysis:

Tests	Specification	Results
Appearance	White to greyish milky liquid, a small amount of sediment is allowed.	complies
Content of original package	min. 10, 20, 50, 100 ml	109 ml
Sterility	The vaccine must be sterile.	sterile
Efficacy	The vaccine must comply the test for efficacy.	complies
Parvovirus component:	<i>Parvovirus suis</i> inact. $\geq 4 \log_2$ *) *) Titer of HI antibodies in serum of guinea pigs after administration of 1/4 volume of vaccination dose	$\geq 4 \log_2$
	The vaccine must be efficacious; 4 of 5 guinea pigs must have titre 1:16 or higher	1: 42.22
Erysipelas component:	<i>Erysipelothrix rhusiopathiae</i> inact. $RP \geq 1^{**}$) **) Relative potency (RP) is determined by comparison with reference preparation conforming to challenge test on target animals according to requirements of Ph. Eur. monograph, as amended.	PEI – 10.37
		PST – 1.72
Identity	Vaccine must comply the test for identity.	complies
Virus inactivation	Parvovirus must be inactive.	complies
Extraneous viruses	Vaccine must create antibodies only against porcine parvovirus.	complies
pH	6.5 – 7.8	6.7
Formaldehyde	Max. 0.19 %	0.05 %
Thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)	0.098 mg/ml
Air tightness	The vials must be hermetically sealed.	complies
Viscosity	1.0 – 4.0 mPa.s	3.9 mPa.s

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. 111, spec.03.




10/09/2019
 Mgr. Hana Nezvalová
 HEAD of QC, QP