

CERTIFICATE OF ANALYSIS

Product: **BioSuis Lepto P, emulsie injectabilă pentru porci**

Batch No.: **50 53 26 A**

Expiry: **04.03.2021**

Date of production: **05.03.2019**

Results of analysis:

Tests	Limit	Results
Appearance	White to pinkish milky liquid which may contain low quantities of the easily dissolvable sediment	complies
Content of original packaging	min. 10 ml, 20 ml, 50 ml	20.0 ml
Sterility	Vaccine must be sterile.	sterile
Efficacy	Vaccine must be effective.	complies
<i>Parvovirus suis</i> inact.	HIT $\geq 4 \log 2$	5.6 log2
<i>Leptospira pomona</i> inact.	ALR ≥ 32	1:102
<i>Leptospira Hardjo</i> inact.	ALR ≥ 32	1:128
<i>Leptospira Bratislava</i> inact.	ALR ≥ 32	1:81
<i>Leptospira grippotyphosa</i> inact.	ALR ≥ 32	1:203
<i>Leptospira icterohaemorrhagiae</i> inact.	ALR ≥ 32	1:81
<i>Leptospira canicola</i> inact.	ALR ≥ 32	1:128
Inactivation - parvovirus component	Vaccine must not contain of live parvovirus. Test is performed as input control.	complies
Inactivation - leptospira component	Vaccine must not contain of live leptospira. Test is performed as input control.	complies
Serum absence	Vaccine must not contain of serum.	complies
Extraneous viruses	The vaccine must create antibodies against the swine parvovirus only.	complies
pH	6.5 – 7.8	7.4
formaldehyde	max 0.190 % (1.9 mg/ml)	0.05 %
thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)	0.113 mg/ml
Airtightness	The vials must be sealed airtight.	complies

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. 158, spec.01.



.....30/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP