

CERTIFICATE OF ANALYSIS

Product: BIOSUIS LEPTO P, emulsie injectabilă

Batch No.: 625928B

Expiry: 9.9.2023

Date of production: 10.9.2021

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White to pinkish milky liquid which may contain low quantities of the easily dissolvable sediment.		complies
Content of original package	min. 10 ml, 20 ml, 50 ml		21.0 ml
Sterility	Vaccine must be sterile.		sterile
Efficacy	Vaccine must be effective.		complies
<i>Parvovirus suis</i> inact.	HIT $\geq 4 \log_2$		5.8 log ₂
<i>Leptospira pomona</i> inact.	ALR ≥ 32		1:64
<i>Leptospira Hardjo</i> inact.	ALR ≥ 32		1:323
<i>Leptospira Bratislava</i> inact.	ALR ≥ 32		1:256
<i>Leptospira grippotyphosa</i> inact.	ALR ≥ 32		1:81
<i>Leptospira icterohaemorrhagiae</i> inact.	ALR ≥ 32		1:161
<i>Leptospira canicola</i> inact.	ALR ≥ 32		1:128
Inactivation ¹ - parvovirus component	Vaccine must not contain of live parvovirus.		complies
Inactivation ¹ - leptospira component	Vaccine must not contain of live leptospira.		complies
Serum absence	Vaccine must not contain of serum.		complies
Extraneous agents	The vaccine must create antibodies against the swine parvovirus only.		complies
pH	6.5 – 7.8		6.7
Formaldehyde	max 0.190 % (1.9 mg/ml)		0.02 %
Thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.108 mg/ml
Air tightness	The vials must be hermetically sealed.		complies

¹ Test is performed as input 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. 158,V002.

27/10/2021
Mgr. Hana Nezvalová
HEAD of QC, QP