



CERTIFICATE OF ANALYSIS

Product: **BIOSUIS ParvoEry L(7), suspensie injectabilă**

Batch No.: **035731A**

Expiry: **06/2026**

Date of production: **9.7.2024**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Appearance		Milky white up to greyish-white liquid. During longer standing the content is divided to limpid liquid and milky white up to greyish sediment.		conforms
Content of original package		min. 10 ml, 50 ml, 100 ml, 250 ml		50.0 ml
Sterility		The preparation shall be sterile.		sterile
Concentration of hydrogen ions (pH)		6.5 – 7.8		7.2
Airtightness		The vials shall be sealed airtight.		conforms
Identification of active substance ⁽¹⁾		The vaccine shall comply with identity test.		conforms
Identification of parvovirus component		The vaccine contains porcine parvovirus.		conforms
Identification of erysipelas component		The vaccine contains <i>Erysipelothrix rhusiopathiae</i> .		conforms
Identification of leptospira component		Specific Leptospira serotype detection.		conforms
Potency ⁽¹⁾		The vaccine shall be effective and should stimulate the specific antibodies formation against porcine parvovirus, against <i>Erysipelothrix rhusiopathiae</i> and individual leptospira strains.		conforms
Potency test of parvovirus component		min. 4.8 log ₂ ⁽²⁾	min. 4 log ₂ ⁽²⁾	7.2 log ₂
Potency test of erysipelas component		RP ≥ 1 ⁽³⁾		1.18
Potency test of leptospira component	LB	min. 100 E.U./dose		498 E.U./dose
	LP	min. 100 E.U./dose		486 E.U./dose
	LC	min. 100 E.U./dose		574 E.U./dose
	LT	min. 100 E.U./dose		635 E.U./dose
	LG	min. 100 E.U./dose		430 E.U./dose
Determination of formaldehyde ⁽¹⁾		Maximum 0.05 % (0.5 mg/ml)		0.048 %
Thiomersal ⁽¹⁾		0.1 mg/ml (0.085 – 0.115 mg/ml)		0.102 mg/ml
Aluminium hydroxide content (Al ₂ O ₃) ⁽¹⁾		0.35 – 0.55 % (3.5 – 5.5 mg/ml)		0.438 %
Residual live virus ⁽⁴⁾		Specific cytopathogenic changes must not occur in the tested cell cultures inoculated with tested sample in comparison with negative control sample. Haemagglutination and occurrence of specific immunofluorescence must not be proved. Test must not prove live virus.		conforms
Residual live bacteria - ER ⁽⁴⁾		The sample must not contain any living germs, there must not be any turbidity in liquid culture medium and/or growth of culture on agar medium.		conforms
Residual live bacteria - Lepto ⁽⁴⁾		The sample must not contain any living germs.		conforms

¹ Performed on bulk

² Titre of haemagglutination-inhibition (HI) antibodies in guinea-pig serum after application of ¼ volume of vaccination dose.

³ Relative potency (RP) is given by comparison with reference preparation (minimal batch) which complied in challenge test on target species according to the requirements of Phr. Eur. monograph in valid form.

⁴ Performed 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. 558,V001.



.....*VZ*.....26/08/2024

Mgr. Hana Nezvalová
HEAD of QC, QP