



CERTIFICATE OF ANALYSIS

Product: **Biocan DHPPi+L lyophilisate for the preparation of injection suspension with diluent**

Batch No.: **126231**

Expiry: **07/2026**

Date of production: **23.8.2024**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction:			
Appearance	Lyophilised vaccine is spongy matter, white or cream to pinkish colour. After dissolving in diluent (L part of the vaccine) the vaccine is white to gray-white, or pink-red to yellowish colour with light opalescence.		conforms
Virus identity:			
Identity CDV:	Neutralisation index ≥ 2 .		3.6
Identity CAV-2:	Neutralisation index ≥ 2 .		4.3
Identity CPV:	Neutralisation index ≥ 2 .		3.2
Identity CPIV-2:	Neutralisation index ≥ 2 .		4.1
Virus titre:			
Virus febris contagiosae canis:	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{3.6}$ TCID ₅₀
Virus laryngotracheitidis contagiosae canis:	min. $10^{3.5}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{4.3}$ TCID ₅₀
Parvovirus enteritidis canis:	min. $10^{4.5}$ TCID ₅₀ , max. $10^{5.5}$ TCID ₅₀		$10^{5.3}$ TCID ₅₀
Virus parainfluenis canis:	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.2}$ TCID ₅₀		$10^{4.1}$ TCID ₅₀
Sterility	Must be sterile.		sterile
Mycoplasma	Vaccine should not contain mycoplasma.		conforms
Extraneous agents	Vaccine should not contain any extraneous agents.		conforms
Residual humidity	Max. 3%.		1.45 %
Vacuum	Residual pressure must be lower than 2.66 Pa.		conforms
Liquid fraction			
Appearance	Whitish or pinkish liquid with easily shakeable sediment.		conforms
Extractable volume	Min. 1 ml.		1.1 ml
Sterility	Must be sterile.		sterile
Inactivation	The vaccine should not contain live leptospira cultures.		conforms
Identity/potency	Leptospira component stimulates the production of specific antibodies. Geometric average of antibody ARL titre must be min. 1:32 after vaccination and revaccination for L. icterohaemorrhagiae, L. canicola and L. grippotyphosa.	L. icterohaemorrhagiae	1: 51
		L. canicola	1: 40
		L. grippotyphosa	1: 256
Aluminium content	1.8 – 2.2 mg/ml.		1.995 mg/ml
Airtightness	Vials should be hermetically closed.		conforms
Reconstituted vaccine:			
Appearance	After dissolving in diluent (L part of the vaccine) the vaccine is white to gray-white, or pink-red to yellowish colour with light opalescence.		conforms
pH	6.5 – 8.0		7.4

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. 144,V004.



06/02/2025
Mgr. Hana Nezvalová
HEAD of QC, QP