

CERTIFICATE OF ANALYSIS

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

Batch No.: **526231**
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 to cream or pinkish colour.		conforms
Virus identity:			
CDV	Neutralisation index ≥ 2 .		3.6
CAV-2	Neutralisation index ≥ 2 .		4.3
CPV	Neutralisation index ≥ 2 .		3.2
CPIV-2	Neutralisation index ≥ 2 .		4.1
Virus titre:			
CDV	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{3.6}$ TCID ₅₀
CAV-2	min. $10^{3.5}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{4.3}$ TCID ₅₀
CPV	min. $10^{4.5}$ TCID ₅₀ , max. $10^{5.5}$ TCID ₅₀		$10^{5.3}$ TCID ₅₀
CPIV-2	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	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. The vaccine should not contain live rabies virus.		conforms
Identity	The leptospira component stimulates the production of specific antibodies.		conforms
	Gemoetric 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: 102
		L. canicola	1: 81
		L. grippotyphosa	1: 406
Potency	The rabies component stimulates the production of specific neutralizing antibodies. Vaccine should contain min. 2 IU/ml.		3.99 IU/ml
Aluminium content	1.8 – 2.2 mg/ml.		2.12 mg/ml
Airtightness	Vials should be hermetically closed.		conforms
Reconstituted vaccine:			
Appearance	After dissolving of lyophilised component in diluent the vaccine is pink-red or yellowish colour with light opalescence.		conforms
pH	6.5 – 8.0		7.5

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. 145,V004.



13/02/2025
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HEAD of QC, QP