

CERTIFICATE OF ANALYSIS

Product: **Mustelvac D**

Batch No.: **445532**

Expiry: **10/2026**

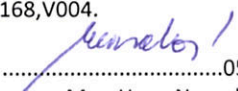
Date of production: **5.5.2025**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried component:			
Appearance	Lyophilised vaccine is spongy matter, white or cream colour.		complies
Distemper virus identity	Neutralisation index ≥ 2 .		3.3
Distemper virus titre (per dose)	The amount of virus in the vaccine reconstituted with 0.5 ml of diluent must be: Virus febris contagiosae canis min. $10^{3.0}$ TCID ₅₀ max. $10^{4.5}$ TCID ₅₀ .		$10^{3.3}$ TCID ₅₀
Mycoplasma	Vaccine must conform.		complies
Extraneous viruses	Vaccine must conform.		complies
Residual humidity	max. 3 %		1.2 %
Vacuum	The vials sealed under vacuum must be evacuated to a residual pressure lower than 2.66 Pa.		conforms
Diluent:			
Appearance	Diluent is clear colourless liquid.		complies
Content of original package	min. 1 ml, 5 ml, 10 ml, 20 ml, 100 ml		101.0 ml
Air tightness	The vial must be hermetically closed.		complies
Sterility	Must be sterile.		sterile
Bacterial endotoxins	Less than 0.25 IU/ml		<0.01 IU/ml
Acid or alkaline-reacting substances	Must comply with the test.		complies
Specific conductivity	max $25 \mu\text{S}\cdot\text{cm}^{-1}$ (for volume 1 ml, 5 ml, 10 ml) max $5 \mu\text{S}\cdot\text{cm}^{-1}$ (for volume 20 ml, 100 ml)		$1.03 \mu\text{S}\cdot\text{cm}^{-1}$
Oxidable substances	Must comply with the test.		complies
Test for chlorides	max 0.5 $\mu\text{g/g}$		<0.5 $\mu\text{g/ml}$
Nitrates	max 0.2 $\mu\text{g/g}$		<0.2 $\mu\text{g/ml}$
Sulphates	Must comply with the test.		complies
Ammonium	max 0.2 $\mu\text{g/g}$		<0.2 $\mu\text{g/ml}$
Calcium and magnesium	Must comply with the test.		complies
Heavy metals	max 0.1 $\mu\text{g/g}$		<0.1 $\mu\text{g/ml}$
Residue after evaporation	max 4 mg (0.004%) (for volume 1ml, 5ml, 10 ml) max 3 mg (0.003%) (for volume 20 ml, 100 ml)		3 mg
Reconstituted vaccine:			
Appearance	After dissolving in diluent the vaccine is clear to yellowish colour with light opalescence.		complies
pH	6.5 – 8.0		7.2
Sterility	Vaccine should be sterile.		sterile

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. 168,V004.




05/06/2025
 Mgr. Hana Nezvalová
 HEAD of QC, QP