

CERTIFICATE OF ANALYSIS

Product: **Biocan DP, liofilizat pentru soluție injectabilă și diluant**

Batch No.: **03 53 26 A**

Expiry: **28.03.2021**

Date of production: **29.03.2019**

Results of analysis:

Tests	Specification	Results
Appearance	Lyophilised vaccine is spongy matter, white to cream or pinkish colour. After dissolving in diluent the vaccine is pink-red to yellowish or whitish colour with light opalescence.	conforms
Mycoplasma	Vaccine should not contain mycoplasma.	conforms
Extraneous viruses	Vaccine should not contain any extraneous viruses.	conforms
Residual humidity	Lyophilised product doesn't contain more than 3% residual humidity.	2.6 %
Airtightness	The vials should be hermetically sealed.	conforms
Sterility	Vaccine should be sterile.	sterile
pH	6.5 – 8.0	7.6
Virus titre:		
CDV – Virus febris contagiosae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.8}$ TCID ₅₀	$10^{3.3}$ TCID ₅₀
CPV – Parvovirus enteritidis canis	min. $10^{4.5}$ TCID ₅₀ , max. $10^{6.0}$ TCID ₅₀	$10^{5.3}$ TCID ₅₀
Virus identity:		
CDV	Neutralisation index ≥ 2 .	3.3
CPV	Neutralisation index ≥ 2 .	3.2
Potency	Vaccine should be efficient.	conforms

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. 140, spec.02.



23/08/2019
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HEAD of QC, QP