

CERTIFICATE OF ANALYSIS

Product: **Biocan Puppy, liofilizat pentru suspensie injectabilă și diluant**

Batch No.: **71 61 26 A**

Expiry: **05.11.2021**

Date of production: **06.11.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Component D:			
Appearance	Spongy consistency, cream or pinkish colour.		conforms
Mycoplasma test	Vaccine should not contain mycoplasma.		conforms
Extraneous viruses	Vaccine should not contain extraneous viruses.		conforms
CDV identity	Neutralisation index ≥ 2 .		4.8
CDV titre	min. $10^{4.2}$ TCID ₅₀ /ml, max. $10^{5.0}$ TCID ₅₀ /ml		$10^{4.8}$ TCID ₅₀ /ml
Residual humidity	max. 3 %		2.2 %
Component P:			
Appearance	White or pink white liquid with fine sediment.		conforms
Package content	Vials should contain min. 1 ml of the vaccine.		1.09 ml
CPV inactivation	In-process control – Parvovirus should be inactivated.		conforms
CPV titre	In-process control – haemagglutination titre min. 1024 HAU, max. 4096 HAU		4 096 HAU
Efficacy	Mean value of antibody titre in sera obtained from guinea-pigs after second vaccination is $\geq 1:80$.		1: 422.2
Airtightness	Vials should be hermetically sealed.		conforms
Content of aluminium hydroxide (measured as Al ₂ O ₃)	1.75 – 2.25 mg/ml		1.92 mg/ml
Disolved vaccine			
Appearance	Liquid of pink-red or yellowish colour with light opalescence.		conforms
pH value	6.5 – 8.0		7.2
Efficacy	Vaccine should be efficient.		conforms
Sterility	Vaccine shall 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. 149.




16/01/2020
 Mgr. Hana Nezvalová
 HEAD of QC, QP