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CERTIFICATE OF ANALYSIS

Product: **Biocan Novel Puppy vakcina A.U.V.**

Batch No.: 04 56 24 A
Expiry: 20.06.2019
Date of production: 21.06.2017

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze - dried fraction			
Appearance	Lyophilized vaccine is spongy consistency, white colour.		complies
Sterility	Vaccine must be sterile.		sterile
Mycoplasma	Vaccine must be free from *mycoplasma*.		complies
Extraneous viruses	Free from extraneous agents.		complies
Virus titre	Function: To determine the virus titre (potency) of each CDV and CPV-2b antigen in the finished product.		complies
CDV	min. $10^{4.7}$TCID$_{50}$ max. $10^{5.5}$ TCID$_{50}$	min. $10^{4.1}$TCID$_{50}$ max. $10^{5.5}$ TCID$_{50}$	$10^{4.8}$ TCID$_{50}$
CPV-2b	min. $10^{6.0}$TCID$_{50}$ max. $10^{7.0}$ TCID$_{50}$	min. $10^{5.5}$TCID$_{50}$ max. $10^{7.0}$ TCID$_{50}$	$10^{6.2}$ TCID$_{50}$
Identity	Function: The test is performed to confirm presence of each CDV and CPV-2b antigen in the finished product.		complies
CDV	Neutralization index has to be equal or higher than 2 log10, NI ≥ 2		4.8
CPV-2b	The CPV type must be CPV 2a, b, c group.		complies
Residual humidity	max. 3 %		1.7 %
Vacuum	The vials sealed under vacuum must be evacuated to a residual pressure lower than 2.66 Pa.		complies
Water for injection - liquid fraction			
Appearance	Clear colourless liquid without smell.		complies
Bacterial endotoxins (Ph. Eur. 2.6.14)	Less than 0.25 IU/ml.		<0.01 IU/ml
Sterility (Ph. Eur. 2.6.1)	The preparation must be sterile.		sterile
Extractable volume (Ph.Eur. 2.9.17)	Minimum 1 ml.		1.1 ml
Air tightness	The vial must be hermetically closed.		complies
Acidity or alkalinity	Must comply with Ph. Eur.		complies
Conductivity	Maximum 25 µS.cm-1		13 µS.cm-1
Oxidisable substances	Must comply with Ph. Eur.		complies
Chlorides	Maximum 0.5 ppm		<0.5 ppm
Nitrates	Maximum 0.2 ppm		<0.2 ppm
Sulfates	Must comply with Ph. Eur.		complies
Ammonium	Maximum 0.6 ppm		<0.6 ppm
Heavy metals	Maximum 0.1 ppm		<0.1 ppm
Calcium and magnesium	Must comply with Ph. Eur.		complies
Residue on evaporation	Maximum 4 mg (0.004 %)		2 mg
Reconstituted Vaccine			
Appearance	Clear, colourless to yellowish liquid with slight opalescence.		complies
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 456.

.....19/12/2017
Mgr. Hana Nezvalová
HEAD of QC, QP