

CERTIFICATE OF ANALYSIS

Product: **Biocan Novel DHPPI, liofilizat și diluant pentru suspensie injectabilă**
Batch No.: **875130**
Expiry: **09/2024**
Date of production: **19.10.2022**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction			
Appearance	Spongy matter, white colour.		conforms
Residual humidity	0.5 - 3 %		1.1 %
Vacuum	Residual pressure must be lower than 2.66 Pa.		conforms
Sterility	Vaccine must be sterile.		sterile
Mycoplasma	Vaccine must be free from <i>mycoplasma</i> .		conforms
Extraneous agents	Free from extraneous agents.		conforms
Virus titre	Function: To determine the virus titre (potency) of each CAV-2, CDV, CPiV-2 and CPV-2b antigen in the finished product.		conforms
CDV	min. $10^{4.0}$ TCID ₅₀ -max. $10^{5.1}$ TCID ₅₀	min. $10^{3.1}$ TCID ₅₀ -max. $10^{5.1}$ TCID ₅₀	$10^{4.3}$ TCID ₅₀
CPV	min. $10^{5.1}$ TCID ₅₀ -max. $10^{6.6}$ TCID ₅₀	min. $10^{4.3}$ TCID ₅₀ -max. $10^{6.6}$ TCID ₅₀	$10^{5.8}$ TCID ₅₀
CAV-2	min. $10^{4.2}$ TCID ₅₀ -max. $10^{5.3}$ TCID ₅₀	min. $10^{3.6}$ TCID ₅₀ -max. $10^{5.3}$ TCID ₅₀	$10^{4.3}$ TCID ₅₀
CPiV-2	min. $10^{3.6}$ TCID ₅₀ -max. $10^{5.1}$ TCID ₅₀	min. $10^{3.1}$ TCID ₅₀ -max. $10^{5.1}$ TCID ₅₀	$10^{5.1}$ TCID ₅₀
Identity	Function: The test is performed to confirm presence of each CAV-2, CDV, CPiV-2 and CPV antigen in the finished product.		conforms
CDV	Neutralization index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CDV.		4.3
CAV-2	Neutralization index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CAV-2.		4.3
CPV-2b	The CPV type must be CPV 2a, b, c group.		conforms
CPiV-2	Neutralization index has to be equal or higher than 2 log ₁₀ and/or specific immunofluorescence has to be seen in the cell culture infected with CPiV.		5.1
Water for injection – liquid fraction			
Appearance	Clear colourless liquid without taste and smell.		conforms
Extractable Volume	minimum 1 ml		1.0 ml
Sterility	The preparation must be sterile.		sterile
Airtightness	The vial must be hermetically closed.		conforms
Acidity or alkalinity	Must comply with Ph. Eur.		conforms
Conductivity	maximum 25 μ S.cm ⁻¹		11.9 μ S.cm ⁻¹
Oxidisable substances	Must comply with Ph. Eur.		conforms
Chlorides	maximum 0.5 ppm.		<0.5 ppm
Nitrates	maximum 0.2 ppm.		<0.2 ppm
Sulphates	Must comply with Ph.Eur.		conforms
Ammonium	maximum 0.6 ppm.		<0.6 ppm
Calcium and magnesium	Must comply with Ph. Eur.		conforms
Residue on evaporation	maximum 4 mg (0.004 %).		4 mg
Bacterial endotoxins	Less than 0.25 IU/ml.		<0.01 IU/ml
Reconstituted Vaccine			
Appearance	Clear whitish to 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. 470.



09/02/2023
Mgr. Hana Nezvalová
HEAD of QC, QP