

CERTIFICATE OF ANALYSIS

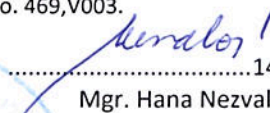
Product: **Biocan Novel Pi/L4, lyofilizat și suspensie pentru suspensie injectabilă**
Batch No.: **405928**
Expiry: **7.7.2023**
Date of production: **8.7.2021**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction			
Appearance	Spongy matter, white colour.		conforms
Residual humidity	0.5 - 3 %		1.2 %
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 CPiV-2 antigen in the finished product.		conforms
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 CPiV-2 antigen in the finished product.		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
Liquid fraction			
Appearance	Whitish liquid with easily shakeable sediments.		conforms
Extractable volume	Minimum 1 ml		1.0 ml
Airtightness	The glass vial must be hermetically sealed.		conforms
Aluminium content *	2 mg/ml (1.8 – 2.2 mg/ml)		1.963 mg/ml
Sterility	Vaccine must be sterile.		sterile
<i>Leptospira</i> inactivation *	No live <i>Leptospira</i> .		conforms
Formaldehyde detection *	The formaldehyde detected has to be below 0.01%.		conforms
<i>Leptospira</i> identity	Vaccine stimulates the production of specific antibodies against each <i>Leptospira</i> serovar.		conforms
<i>Leptospira</i> potency	Minimum of 1:64 ALR geometric mean titre, for each <i>Leptospira</i> serovar.	Minimum of 1:51 ALR geometric mean titre for <i>L. Icterohaemorrhagiae</i> .	1: 72
		Minimum of 1:51 ALR geometric mean titre for <i>L. Canicola</i> .	1: 81
		Minimum of 1:51 ALR geometric mean titre for <i>L. Bratislava</i> .	1: 128
		Minimum of 1:40 ALR geometric mean titre for <i>L. Grippotyphosa</i> .	1: 128
Reconstituted Vaccine			
Appearance	Whitish to yellowish liquid with light opalescence.		conforms
pH	6.8 – 7.8		7.6

* tests carried out during manufacturing process of liquid fraction

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. 469,V003.


14/02/2022
 Mgr. Hana Nezvalová
 HEAD of QC, QP