

CERTIFICATE OF ANALYSIS

Product: **Biocan Novel DHPPI/L4, lyofilizat și diluant pentru suspensie injectabilă**

Batch No.: **64 58 25**

Expiry: **14.11.2019**

Date of production: **15.11.2017**

Results of analysis:

Tests	Release limits		Shelf-life limits	Results
Freeze-dried fraction				
Appearance	Spongy matter, white colour.			conforms
Residual humidity	0.5 - 3 %			2.0 %
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 ^{5.1} 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 ^{6.6} 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 ^{4.6} 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 ^{4.8} 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.			5.1
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.			4.6
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.			4.8
Liquid fraction				
Appearance	Whitish liquid with easily shakeable sediments.			conforms
Extractable volume	Minimum 1 ml			1 ml
Airtightness	The glass vial must be hermetically sealed.			conforms
Aluminium content *	2 mg/ml (1.8 – 2.2 mg/ml)			1.9 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: 161
		Minimum of 1:51 ALR geometric mean titre for <i>L. Bratislava</i> .		1: 72
		Minimum of 1:40 ALR geometric mean titre for <i>L. Grippotyphosa</i> .		1: 81
Reconstituted Vaccine				
Appearance	Pinkish or yellowish colour with light opalescence.			conforms
pH	6.8 – 7.8			7.4

* tests carried out during manufacturing process of liquid fraction of Biocan Novel DHPPI/L4, lyofilizat și diluant pentru suspensie injectabilă.
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. 465.



05/12/2018
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HEAD of QC, QP