



CERTIFICATE OF ANALYSIS

Product: **BIOCAN DHPPi+L vakcina A.U.V.**

Batch No.: **31 59 25**

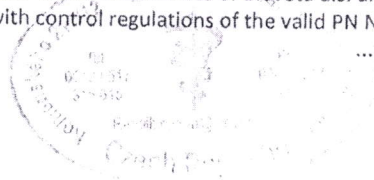
Expiry: **05.07.2020**

Date of production: **06.07.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction:			
Appearance	Lyophilised vaccine is spongy matter, white or cream to pinkish colour. After dissolving in diluent (L part of the vaccine) the vaccine is white to gray-white, or pink-red to yellowish colour with light opalescence.		conforms
Mycoplasma	Vaccine should not contain mycoplasma.		conforms
Extraneous viruses	Vaccine should not contain extraneous viruses.		conforms
Residual humidity	Lyophilised product should not contain more than 3% of residual humidity.		2.0 %
Vacuum	The vials with vaccine must be evacuated for residual pressure lower than 2.66 Pa.		conforms
Virus titre:			
CDV – Virus febris contagiosae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{4.3}$ TCID ₅₀
CAV-2 – Virus laryngotracheitidis contagiosae canis	min. $10^{3.5}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀		$10^{4.3}$ TCID ₅₀
CPV – Parvovirus enteritidis canis	min. $10^{4.5}$ TCID ₅₀ , max. $10^{5.5}$ TCID ₅₀		$10^{5.1}$ TCID ₅₀
CPIV-2 – Virus parainfluenzis canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.2}$ TCID ₅₀		$10^{3.3}$ TCID ₅₀
Virus identity			
CDV	Neutralisation index ≥ 2 .		4.3
CAV-2	Neutralisation index ≥ 2 .		4.3
CPV	Neutralisation index ≥ 2 .		3.0
CPIV-2	Neutralisation index ≥ 2 .		3.3
Liquid fraction:			
Appearance	Whitish or pinkish liquid with easily shakeable sediment.		conforms
Content of original package	Min. 1 ml.		1.1 ml
Content of aluminium oxide	2 mg/ml (1.8 – 2.2 mg/ml).		2.04 mg/ml
Airtightness	Vial should be hermetically closed.		conforms
Efficacy and identity	Leptospira component stimulates the production of specific antibodies. Geometric average of antibody ARL titre has to be 1:32 after vaccination and revaccination rabbits. Vaccine should be effective.	L. icterohaemorrhagiae	1 : 51
		L. canicola	1 : 81
		L. grippotyphosa	1 : 256
Inactivation	The vaccine should not contain live leptospira cultures.		conforms
Serum absence	The vaccine should not contain serum (in-process control).		conforms
Reconstituted vaccine:			
Appearance	After dissolving in diluent (L part of the vaccine) the vaccine is white to grey-white, or pink-red to yellowish colour with light opalescence.		conforms
Sterility	Vaccine should be sterile.		sterile
pH	6.5 – 8.0		7.3

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. 144.



.....12/10/2018
 Mgr. Hana Nezvalová
 HEAD of QC, QP

Bioveta, a.s. Ivanovice na Hané	BIOCAN DHPPI+L vakcina A.U.V. Hungary	ID code: BPR00129 Page: 1 of 25 Enclosures: 0 Version: V001 Copy No.:
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1. MEMBER STATE SPECIFIC INFORMATION

Identification number for batch to be placed on the market in the Member State (if packaging number different from final number in section 2)	31 59 25
Marketing authorisation number issued by (Member State/EU)	2500/1/09 MgSzHÁTI (1 adag)
Target species	Dog (Canis familiaris, L.) at the age of 8 weeks and above
Total number of containers in this batch (pcs)	4 010 pcs
Number of containers the release is applied for	401 x 10 x 1 dose
Number of doses per container	one dose
Number of samples for the competent authority	-
Date of expiry	05.07.2020
Name and address of Marketing Authorisation holder	Alpha – Vet Animal Health Ltd. Homokosor 7 8000 Székesfehérvár Hungary