



CERTIFICATE OF ANALYSIS

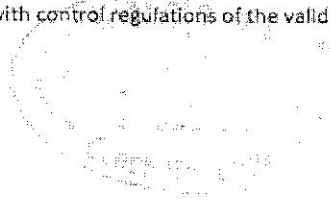
Product: **BIOCAN DHPPi+L vakcina A.U.V**

Batch No.: **10 51 22**
 Expiry: **25.11.2016**
 Date of production: **26.11.2014**

Results of analysis:

Tests	Specification	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.	0,93 %
Vacuum	The vials with vaccine must be evacuated for residual pressure lower than 2.65 Pa.	conforms
Virus titre:		
CDV – Virus febris contagiosae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀	$10^{4.1}$ TCID ₅₀
CAV-2 – Virus laryngotracheitidis contagiosae canis	min. $10^{3.5}$ TCID ₅₀ , max. $10^{4.5}$ TCID ₅₀	$10^{3.8}$ TCID ₅₀
CPV – Parvovirus enteritidis canis	min. $10^{4.5}$ TCID ₅₀ , max. $10^{5.5}$ TCID ₅₀	$10^{5.3}$ TCID ₅₀
CPiV-2 – Virus parainfluenzae canis	min. $10^{3.0}$ TCID ₅₀ , max. $10^{4.2}$ TCID ₅₀	$10^{4.1}$ TCID ₅₀
Virus identity		
CDV	Neutralisation index ≥ 2 .	4.1
CAV-2	Neutralisation index ≥ 2 .	3.8
CPV	Neutralisation index ≥ 2 .	3.2
CPiV-2	Neutralisation index ≥ 2 .	4.1
Liquid fraction:		
Appearance	Whitish liquid with easily shakeable sediment.	conforms
Content of original package	min. 1 ml	1.09 ml
Content of aluminium oxide	2 mg/ml (1.8 – 2.2 mg/ml).	1.832 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 min. 32 after vaccination and revaccination of rabbits. Vaccine should be effective.	1 : 94
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 the vaccine is pink-red or yellowish colour with light opalescence.	conforms
Sterility	Vaccine should be sterile.	sterile
pH	6,5 – 8,0	7,94

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.



Hana Nezvalová
20/03/2015
 Mgr. Hana Nezvalová
 HEAD of QC