

CERTIFICATE OF ANALYSIS

Product: **BIOCAN LR**

Batch No.: **57 61 25 A**

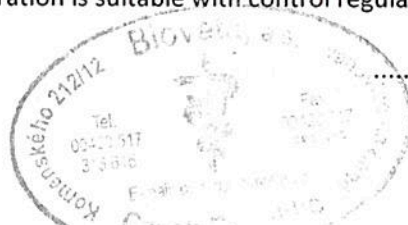
Expiry: **31.10.2020**

Date of production: **01.11.2018**

Results of analysis:

Tests	Specification	Results
Appearance	Whitish liquid with easily shakeable sediment.	conforms
Content of original package	min. 1 ml	1.1 ml
Sterility	Vaccine should be sterile.	sterile
Inactivation (in-process control) – L component	The vaccine should not contain live leptospira cultures.	conforms
Inactivation (in-process control) – R component	The vaccine should not contain live rabies virus.	conforms
Serum absence (in-process control)	The vaccine should not contain serum.	conforms
pH	6.5 – 8.0	7.7
Content of aluminium hydroxide (measured as Al ₂ O ₃)	Aluminium oxide content – 2 mg/ml (1.8 – 2.2 mg/ml).	1.82 mg/ml
Airtightness	Vial should be hermetically closed.	conforms
Antigen titre:		
Virus rabiei inact.	min. 2 IU, max. 4 IU	2.95 IU
L.icterohaemorrhagiae inact	min. 1x10 ^{7.0} TCID ₅₀ , max. 1x10 ^{9.0} TCID ₅₀	7x10 ^{7.0} TCID ₅₀
L. canicola inact.	min. 1x10 ^{7.0} TCID ₅₀ , max. 1x10 ^{9.0} TCID ₅₀	7x10 ^{7.0} TCID ₅₀
L. grippotyphosa inact.	min. 1x10 ^{7.0} TCID ₅₀ , max. 1x10 ^{9.0} TCID ₅₀	7x10 ^{7.0} TCID ₅₀
Efficacy and identity:		
L component:	Vaccine must be efficient. Geometric average of antibody ARL titre must be min. 1:32 after vaccination and revaccination for L. icterohaemorrhagiae, L. canicola and L. grippotyphosa.	L. icterohaemorrhagiae 1: 32
		L. canicola 1: 51
		L. grippotyphosa 1: 32
R component:	The rabies component stimulates the production of specific neutralizing antibodies. Vaccine should contain min. 2 IU and max. 4 IU (vaccination dose).	conforms

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. 150, spec.02.



14/01/2019
Mgr. Hana Nezvalová
HEAD of QC,QP