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QCZD229QCX3061

ANALYSIS CERTIFICATE

Product	CANVAC 8 DHPPiL lyophilizate and solvent for suspension for injection for dogs
Batch No.	130519
Volume	119 packs 30 x 1 dose Romania
Manufacture Date	2019-05-09
Expiry Date	10/2020

Appearance: The lyophilized suspension is a light-pink, or yellowish, porous, compact or crumbled mass. The solvent is a colourless clear liquid. Mixing results in a light-pink or yellowish liquid.

Packing size: 1 ml of freeze-dried suspension, i.e. one dose is in a 3-ml vial, 1 ml of diluent for 1 dose is in a 3-ml vial.

Tests		
Analysis	Specification	Results
Utilizable volume of a solvent	Utilizable volume of a solvent must be higher than nominal volume	Passed
Residual Humidity	NMT 3.00 %	Passed
pH Volume	6.50 to 7.50	7.21
Airtightness	The vials must be airtight closed	Passed
Sterility	The product must be sterile	Passed
Absence of live mycoplasma	The product must not contain live mycoplasma	Passed
Identity	Identity must be proven	Passed
Safety	The product must be safe	Passed
Efficacy	D-virus febris contagiosae canis attenuatum $10^{2.7} - 10^{4.5}$ EID ₅₀ in 1 ml	3.45
	H, La-virus laryngotracheitidis contagiosae canis attenuatum $10^{3.5} - 10^{7.5}$ CCID ₅₀ in 1 ml	6.00
	P-parvovirus enteritidis canis attenuatum $10^{2.1} - 10^{3.6}$ HAU ₅₀	2.71
	Pi-virus parainfluenzae canis attenuatum $10^{3.0} - 10^{6.0}$ CCID ₅₀ in 1 ml	4.66
	Leptospira grippotyphosa – amount inducing in experimental animals serological response reaching neutralizing antibody titre NLT 1:32	96
	Leptospira icterohaemorrhagiae – amount inducing in experimental animals serological response reaching neutralizing antibody titre NLT 1:32	96
	Leptospira sejroe – amount inducing in experimental animals serological response reaching neutralizing antibody titre NLT 1:32	96

Date of Issue	2019-08-16	Valid till:	10/2020
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