

CERTIFICATE OF ANALYSIS

Product: **PESTORIN MORMYX, liofilizat ,i solvent pentru suspensie injectabili**

Batch No.: **79 58 27**
Expiry: **22.4.2022**
Date of production: **23.4.2020**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Liquid component				
Appearance		White or greyish white liquid containing fine sediment.		conforms
Extractable volume		min. 1 ml, min. 5 ml, min. 10 ml, min. 20 ml		10.4 ml
Sterility		The preparation shall be sterile.		sterile
pH		6.5 – 7.5		7.5
Content of aluminium oxide		0.2 – 0.6 %		0.43 %
Thiomersalum content		0.0085 – 0.0115 %		0.0096 %
Airtightness		The vials shall be hermetically sealed.		conforms
Identity test		The presence of the specific antibodies against RHDV having the titre of at least 80 shall be proved in the serum of the vaccinated animals		conforms
Freeze-dried component:				
Appearance		Lyophilized vaccine is yellowish colour and spongy structure.		conforms
Sterility		Vaccine must be sterile.		sterile
Mycoplasma test		Free from mycoplasma.		conforms
Proof of extraneous agents		Free from antibodies against rabbit haemorrhagic disease virus.		conforms
Identity test		The positive control shall exhibit the apparent positive reaction, the negative control shall exhibit absence of the specific fluorescence.		conforms
Titre of myxomatosis virus		MXT virus attenuated strain CAMP V-219: vaccine titre $10^{3.3}$ TCID ₅₀ /1 ml - $10^{5.8}$ TCID ₅₀ /1 ml		$10^{3.8}$ TCID ₅₀ /1 ml
Residual humidity		Max. 3 %		1.7 %
Vacuum		The vials shall be evacuated to the residual pressure lower than 2.66 Pa		conforms
Diluted vaccine:				
Appearance		Reconstituted vaccine is white or greyish white liquid or slightly pinkish containing fine sediment.		conforms
Sterility		Vaccine shall be sterile.		sterile
pH		6.5 – 7.5		7.4
Residual live virus /previously safety/		The vaccine complies with the test if no rabbit shows notable signs of disease or dies from causes attributable to the vaccine.		safe
Potency	RHD component	The vaccine meets the requirements specified for the efficacy testing if at least 90 % of vaccinated animals survive during the specified monitoring period.		conforms
		The vaccine meets the requirements specified for efficacy testing if the average titre of HI antibodies of at least 1:80 is found out in the vaccinated rabbits.		conforms
		RHD virus inactivated strain CAMP V-351: Min. 128 – max. 1024 HAU *		819.0 HAU
	MXT component	The result of the test is acceptable if during the 21-day monitoring period at least 90 % of vaccinates resist to the infection by myxoma virus.**		conforms

Note: * The test is carried out as the in-process control /**The efficacy test by challenge is always performed with the first batch of the vaccine produced from the new batch of the working seed lot, but at least once per year

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. 195.




1/10/2020
 Mgr. Hana Nezvalová
 HEAD of QC, QP