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CERTIFICATE OF ANALYSIS

Product: **PESTORIN MORMYX vakcina A.U.V.**
Vaccine against rabbit haemorrhagic disease and myxomatosis

Batch No.: **40 53 22**
Expiry: 31.08.2016
Date of production: 01.09.2014

Results of analysis:

Tests	Specification	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	1.10 ml
Sterility	The preparation stall be sterile.	sterile
pH	6.5 – 7.5	7.30
Content of aluminum oxide	0.2 – 0.6 %	0.339 %
Thiomersalum content	0.0085 – 0.0115 %	0.0101 %
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 white up to 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	vaccine titre $10^{3.3}$ $TCID_{50}$/1 ml - $10^{5.8}$ $TCID_{50}$/1 ml	$10^{4.8}$ $TCID_{50}$/1 ml
Residual humidity	max. 3 %	2.73 %
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 up to yellowish liquid containing fine sediment.	conforms
Sterility	Vaccine shall be sterile.	sterile
pH	6.5 – 7.5	7.21
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:		
Against Haemorrhagic disease	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
Against myxomatosis *	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. /* 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./	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. 195, spec.03.

.....20/04/2015
Mgr. Hana Nezvalová
HEAD of QC, QP