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CERTIFICATE OF ANALYSIS

Product: **BioEquin FH vakcina A.U.V., emulziós injekció lovaknak**

Batch No.: **16 53 24 A**
Expiry: 05.09.2018
Date of production: 06.03.2017

Results of analysis:

Tests	**Release limits**	**Shelf-life limits**	**Results**
Appearance	Vaccine is a white, oily liquid with easily shakeable sediment.		conforms
Extractable volume	min. 1 ml, 5 ml		1.1 ml
Sterility	Vaccine must be sterile.		sterile
Identity and potency**:			
A/Equi 2/Brno 08	≥ 6 log_2 HIT[1]		7.4 log_2 HIT[1]
A/Equi 2/ Morava 95	≥ 6 log_2 HIT[1]		9.2 log_2 HIT[1]
EHV-1	≥ 2.1 log_{10} VNI[2]		3.1 VNI[2]
** Performed on bulk of vaccine [1] Geometric mean of specific antibodies determined by haemagglutination inhibition test in the guinea pig serum [2] Virus neutralization index			
Inactivation* (Residual live virus)	No live virus is detected.		conforms
	No haemagglutionation occurs * Performed as in-process control.		conforms
Hydrogen ionsconcentration determination	pH = 6.5 – 7.5		7.3
Content of thiomersal	0.085 – 0.115 mg /ml		0.094 mg/ml
Air-tightness	Vials must be hermetically closed.		conforms
Viscosity	2.5 – 5.5 mPa.s		3.7 mPa.s

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. 207, spec.02.

.....13/11/2017
Mgr. Hana Nezvalová
HEAD of QC, QP