

CERTIFICATE OF ANALYSIS

Product: **BioEquin FH, emulsie injectabilă pentru cai**

Batch No.: **035430A**

Expiry: **09/2024**

Date of production: **21.4.2023**

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 $\geq 6 \log_2$ HIT ¹		8.6 $\log_2$ HIT ¹
	A/Equi 2/ Limerick 2010 $\geq 6.8 \log_2$ HIT ¹	A/Equi 2/ Limerick 2010 $\geq 6 \log_2$ HIT ¹	8.4 $\log_2$ HIT ¹
	EHV-1 $\geq 2.1 \log_{10}$ VNI ²		2.2 VNI ²
Inactivation* (Residual live virus)	No haemagglutination occurs		conforms
	No live virus is detected		conforms
Hydrogen ions concentration determination	pH = 6.5 – 7.5		7.1
Content of thiomersal	0.085 – 0.115 mg/ml		0.099 mg/ml
Air-tightness	Vials must be hermetically closed.		conforms
Viscosity	2.5 – 5.5 mPa.s		3.8 mPa.s

¹ Geometric mean of specific antibodies determined by haemagglutination inhibition test in the guinea pig serum

² Virus neutralization index

* Performed as in-process control.

** Performed on bulk of vaccine

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. 548, V004.



30/5/2023
Mgr. Hana Nezvalová
HEAD of QC, QP