

CERTIFICATE OF ANALYSIS

Product: **BioEquin FT, suspensie injectabilă**

Batch No.: **125632A**

Expiry: **02/2028**

Date of production: **27.6.2025**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White or yellowish to greyish brown suspension, during storage can settle down sediment disperses after shaking.		complies
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	A/Equi 2/Brno 08 $\geq 5 \log_2$ HIT ¹	8.6 $\log_2$ HIT
	A/Equi 2/Limerick 2010 $\geq 6.4 \log_2$ HIT ¹	A/Equi 2/Limerick 2010 $\geq 5 \log_2$ HIT ¹	7.2 $\log_2$ HIT
	Tetanus min. 30 IU ²		35.53 IU
Inactivation**	No haemagglutination occurs		complies
Bacterial endotoxins**	Max. 100 IU/1ml		complies
Content of aluminium oxide	3.5 – 4.5 mg/ml		3.7 mg/ml
pH	6.8 – 7.8		7.79
Content of thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.097 mg/ml
Air-tightness	Vials must be hermetically closed.		complies

1 Serum antibody titre determined in haemagglutination inhibition test after application of one vaccine dose to guinea pigs.

2 International units; titre of anti-toxin antibodies, induced after repeated vaccination of guinea pigs according to Ph. Eur., as determined by ELISA.

* Performed on bulk of vaccine

** Performed as in-process control.

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. 553,V001.



29/09/2025
Mgr. Hana Nezvalová
HEAD of QC, QP