

CERTIFICATE OF ANALYSIS

Product: **FLUEQUIN T, suspensie injectabilă**

Batch No.: **31 53 25 A**

Expiry: **20.03.2021**

Date of production: **21.03.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White up to greyish white fluid with fine sediment.		conforms
Content of the original package	Min. 1 ml, 5 ml		1.1 ml
Sterility	The vaccine must be sterile.		sterile
Residual toxicity	The vaccine complies with the test if no animal shows notable signs of disease or dies from causes attributable to the vaccine. The vaccine doesn't comply with the test if within 21 days of the injection any of animals shows signs of or dies from tetanus. If more than 1 animal dies from non-specific causes, repeat the test. If any animal dies in the 2 nd test, the vaccine does not comply.		conforms
Inactivation*	The vaccine must be inactivated.		conforms
Efficacy	The vaccine must be effective.		conforms
Identity	The vaccine induces formation of antibodies.		conforms
pH	6.5 – 7.5		7.5
Aluminium oxide content	3.5 – 4.5 mg/ml		3.84 mg/ml
Thiomersal content	0.1 mg/ml (0.085 – 0.115)		0.102 mg/ml
Air tightness	The vials must be hermetically sealed.		conforms

* 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. 210.



Handwritten signature
21/03/2019
Mgr. Hana Nezvalová
HEAD of QC, QP