

CERTIFICATE OF ANALYSIS

Product: **TRICHOBEN, liofilizat si diluant pentru suspensie injectabila**

Batch No.: **835328A**

Expiry: **21.3.2024**

Date of production: **22.3.2021**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Brownish grey lyophilizate of a porous structure. After diluted with the relevant dilutor the suspension of milky colour with greyish brown sediment that disperses uniformly after the liquid is shaken is formed. Fine unshakeable particles are agar residua that pass through a filter and do not impair product efficacy.		conforms
Bacterial sterility and purity	Vaccine must contain a pure culture of <i>Trichophyton verrucosum</i> .		sterile
Number of CFU/ml	Vaccine must contain 3.125×10^6 - 18.75×10^6 CFU/ ml of the vaccination strain.		7.400×10^6 CFU/ml
Efficacy	The vaccine must be efficacious for cattle after an intramuscular application. The test is to be executed in the case of MSL changes.		conforms
Hydrogen ion concentration	pH 6.0 – 7.5		7.0
Vacuum	The vial must be evacuated to a residual pressure lower than 2.66 Pa		conforms
Residual humidity	max. 3 %		1.7 %
Reconstitution test	The lyophilizate should be shaken completely in 5 minutes to a homogeneous suspension.		conforms

Diluent A

Tests	Release limits	Shelf-life limits	Results
Appearance	Colourless, pellucid solution without sediment.		conforms
Sterility test	The preparation must be sterile.		sterile
Extractable volume	Presentation 10.0 ml - vials 10 ml – fill volume 10.2 ml Presentation 40.0 ml - vials 50 ml – fill volume 40.5 ml Presentation 80.0 ml - vials 100 ml – fill volume 80.5 ml		40.1 ml
pH	6.5 – 7.8		7.5
Airtightness	The vials must be airtight sealed.		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. 238.



[Signature]
.....23/4/2021
Mgr. Hana Nezvalová
HEAD of QC, QP