

## CERTIFICATE OF ANALYSIS

Product: **TRICHOBEN, liofilizat si diluant pentru suspensie injectabila**Batch No.: **245728A**Expiry: **11.7.2024**Date of production: **12.7.2021**

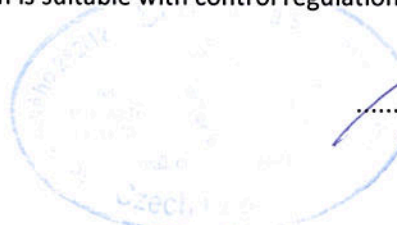
## Results of analysis:

| 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 $3.125 \times 10^6$ - $18.75 \times 10^6$ CFU/ ml of the vaccination strain.                                                                                                                                                                                                                              |                   | $8.000 \times 10^6$ 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 %                                                                                                                                                                                                                                                                                                                       |                   | 1.4 %                      |
| 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<br>Presentation 40.0 ml - vials 50 ml – fill volume 40.5 ml<br>Presentation 80.0 ml - vials 100 ml – fill volume 80.5 ml |                   | 40.0 ml  |
| pH                 | 6.5 – 7.8                                                                                                                                                                         |                   | 7.4      |
| 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.



.....18/8/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP