

## CERTIFICATE OF ANALYSIS

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

Batch No.: **22 56 26 A**

Expiry: **19.12.2020**

Date of production: **20.06.2019**

### Results of analysis:

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                                                                                                                                                                                                                               | $\geq 6 \log_2 \text{ HIT}^1$                                   |                   | $7.0 \log_2 \text{ HIT}^1$ |
| A/Equi 2/ Morava 95                                                                                                                                                                                                                            | $\geq 6 \log_2 \text{ HIT}^1$                                   |                   | $7.2 \log_2 \text{ HIT}^1$ |
| EHV-1                                                                                                                                                                                                                                          | $\geq 2.1 \log_{10} \text{ VNI}^2$                              |                   | $2.5 \text{ VNI}^2$        |
| <sup>1</sup> Geometric mean of specific antibodies determined by haemagglutination inhibition test in the guinea pig serum<br><sup>2</sup> Virus neutralization index<br>* Performed as in-process control.<br>** Performed on bulk of vaccine |                                                                 |                   |                            |
| Inactivation*                                                                                                                                                                                                                                  | No haemagglutination occurs                                     |                   | conforms                   |
| (Residual live virus)                                                                                                                                                                                                                          | No live virus is detected                                       |                   | conforms                   |
| Hydrogen ions concentration determination                                                                                                                                                                                                      | pH = 6.5 – 7.5                                                  |                   | 7.0                        |
| Content of thiomersal                                                                                                                                                                                                                          | 0.085 – 0.115 mg/ml                                             |                   | 0.113 mg/ml                |
| Air-tightness                                                                                                                                                                                                                                  | Vials must be hermetically closed.                              |                   | conforms                   |
| Viscosity                                                                                                                                                                                                                                      | 2.5 – 5.5 mPa.s                                                 |                   | 4.5 mPa.s                  |

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. 207.



.....11/09/2019  
Mgr. Hana Nezvalová  
HEAD of QC, QP

