



## CERTIFICATE OF ANALYSIS

Product: **SER CLOSTETAN, produs injectabil**

Batch No.: **645929A**

Expiry: **08/2024**

Date of production: **14.9.2022**

### Results of analysis:

| Tests                       | Release limits                                                                                                                                                                     | Shelf-life limits | Results  |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------|
| Appearance                  | Clear, brownish up to brownish green, slightly opalescent liquid. Serum, if left stand for a certain period of time, forms fine sediment that disperses when the liquid is shaken. |                   | complies |
| Content of original package | min. 20 ml, min. 100 ml                                                                                                                                                            |                   | 20.0 ml  |
| Sterility                   | Product must be sterile.                                                                                                                                                           |                   | sterile  |
| Safety                      | Product must be safe.                                                                                                                                                              |                   | complies |
| Efficacy                    | The product must be effective, a minimum titer of antibodies in 1 ml - 300 IU.                                                                                                     |                   | complies |
| Extraneous proteins         | Must be proven presence of equine proteins only.                                                                                                                                   |                   | complies |
| Overall content of proteins | 60 – 80 g/l                                                                                                                                                                        |                   | 71.6 g/l |
| Phenol                      | max. 0.5 %                                                                                                                                                                         |                   | 0.38 %   |
| pH                          | 7.0 – 8.0                                                                                                                                                                          |                   | 7.7      |
| Air tightness               | The vials must be hermetically sealed.                                                                                                                                             |                   | complies |

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. 212,V005.



3/11/2022  
Mgr. Hana Nezvalová  
HEAD of QC, QP