

CERTIFICATE OF ANALYSIS

Product: **SER CLOSTETAN, produs injectabil**Batch No.: **725730B**Expiry: **06/2025**Date of production: **13.7.2023**

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		22.0 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		64.2 g/l
Phenol	max. 0.5 %		0.32 %
pH	7.0 – 8.0		7.6
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.




15/8/2023
Mgr. Hana Nezvalová
HEAD of QC, QP