

CERTIFICATE OF ANALYSIS

Product: **AVITUBAL 25.000, solutie injectabila**

Batch No.: **82 54 27 A**

Expiry: **06.04.2022**

Date of production: **07.04.2020**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear liquid, free of flakes and sediment with characteristic odor of phenol.		conforms
Content of the original package	min. 1, 2, 5, 10, 20 ml		1.0 ml
Sterility	The preparation must be sterile.		sterile
Efficacy	The preparation must be efficacy. The preparation must contain 25.000 ± 7.000 IU in 1 ml.		26 037 IU/ml
Identity	Must not cause changes in healthy animals after intradermal administration.		conforms
Toxicity test	Must not cause any abnormal reactions in healthy animals after subcutaneous administration.		conforms
Senzibilization test	The preparation must not evoke guinea-pigs sensitization after repeated administration.		conforms
Phenol	max. 0.5 %		0.42 %
pH	6.5 – 7.5		7.3
Air tightness	The vials must be hermetically 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. 175.



Hana Nezvalová
Mgr. Hana Nezvalová
HEAD of QC, QP

14/05/2020