

CERTIFICATE OF ANALYSIS

Product: **BioBos Mastiguard, suspensie injectabilă**Batch No.: **016131A**Expiry: **10/2026**Date of production: **8.11.2024**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Appearance		A light liquid with greyish sediment of aluminium hydroxide. Grey turbid liquid without coarse insoluble particles after shaking		conforms
Extractable volume		Min. 10 ml, 50 ml, 100 ml		10.3 ml
Air tightness		The vial must be hermetically sealed.		conforms
Sterility		The product must be sterile.		sterile
pH		6.5 – 7.7		7.09
Potency*	<i>E.coli</i>	$1.37 \leq RP \leq 3.40$	$RP \geq 1$	1.58
	<i>S. aureus</i>	$1.43 \leq RP \leq 3.51$	$RP \geq 1$	1.65
Identity*		Identity is confirmed by the production of antibodies against the declared antigens in healthy animals without antibodies vaccinated in the efficacy test.		conforms
Aluminium content*		2.9 – 4.3 mg/ml		3.82 mg/ml
Thiomersal content*		0.085 – 0.115 mg/ml		0.109 mg/ml
Endotoxins assay **		Max. 1.95×10^6 EU/dose		7.11×10^5 EU/dose
Formaldehyde content*		Max. 0.05 %		0.002 %

*performed as an in-process control on bulk vaccine

**performed on bacterin just before vaccine bulk formulation

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. 527,V001.



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.....20/02/2025
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HEAD of QC, QP