

CERTIFICATE OF ANALYSIS

Product: **BioBos IBR marker live – liofilizat si solvent pentru suspensie**

Batch No.: **455431A**

Expiry: **03/2026**

Date of production: **15.4.2024**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Lyophilised vaccine is spongy matter, cream, yellowish to pinkish colour. After dissolving in diluent the vaccine is pinkish-red or yellowish colour with light opalescence.		complies
Sterility	The vaccine must be sterile.		sterile
Mycoplasma	The vaccine must not contain mycoplasma.		complies
Extraneous viruses	The vaccine must not contain extraneous viruses.		complies
Efficacy	The vaccine must be effective.		complies
	min. $10^{6.3}$ TCID ₅₀ / 2 ml max. $10^{7.5}$ TCID ₅₀ / 2 ml	min. $10^{5.7}$ TCID ₅₀ / 2 ml max. $10^{7.5}$ TCID ₅₀ / 2 ml	$10^{6.5}$ TCID ₅₀ / 2 ml
Identity	Identity of BHV 1 Bio 27 (gE-) virus is confirmed when the amplicon for gB is detected and concurrently amplicon for gE is not detected.		complies
pH	6.5 – 8.0		7.4
Residual humidity	max. 3 %		0.3 %
Vacuum	The vial must be evacuated for residual pressure lower than 2.66 Pa.		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. 185,V002.




.....17/05/2024
Mgr. Hana Nezvalová
HEAD of QC, QP