



CERTIFICATE OF ANALYSIS

Product: **BioBos Respi 5, liofilizat și suspensie pentru suspensie injectabilă**
Batch No.: **165731**
Expiry: **03/2026**
Date of production: **18.4.2024**

Results of analysis:

Tests		Release limits		Shelf-life limits	Results
Freeze-dried fraction					
Appearance		A spongy consistency, a cream to yellowish colour.			conforms
Sterility		The product must be sterile.			sterile
Mycoplasma		The vaccine must be free from mycoplasma.			conforms
Extraneous agents		The vaccine must be free from extraneous agents.			conforms
Potency (virus titre)		min. $10^{6.3}$ TKID ₅₀ / 2 ml, max. $10^{7.5}$ TKID ₅₀ / 2 ml	min. $10^{5.7}$ TKID ₅₀ / 2 ml, max. $10^{7.5}$ TKID ₅₀ / 2 ml		$10^{6.5}$ TKID ₅₀ / 2 ml
Identity		The identity of the virus BHV 1 Bio 27 (gE-) is confirmed if the amplicon for gB is detected and, simultaneously, the amplicon for gE is not detected.			conforms
pH		7.2 – 8.0			7.5
Residual humidity		0.05 - 3 %			0.2 %
Vacuum		The vial must be evacuated to a residual pressure of less than 2.66 Pa.			conforms
Liquid fraction					
Appearance		Rosy liquid with sediment.			conforms
Content of the original package	10 ml	Min. 10 ml			--- ml
	50 ml	Min. 50 ml			50.0 ml
Sterility test		The vaccine must be sterile.			sterile
Quillaia Saponin III Assay		0.2 – 0.3 mg/2 ml			0.258 mg/2 ml
Relative potency	PI-3	RP ≥ 1.17	RP ≥ 1		1.26
	BRSV	RP ≥ 1.15	RP ≥ 1		1.28
	BVD	RP ≥ 1.18	RP ≥ 1		1.39
	<i>Mannheimia haemolytica</i>	RP ≥ 1.16	RP ≥ 1		1.32
	Leucotoxin of <i>Mannheimia haemolytica</i>	min. RP ≥ 1.88 max. RP ≤ 7.65	RP ≥ 1		2.30
Identity test		The vaccine stimulates the production of specific antibodies against declared antigens			conforms
pH		6.5 – 7.5			7.4
Bacterial endotoxins assay*		Max. $1.86 \times 10^{4.0}$ EU / vaccination dose (2ml)			2.03×10^3 EU/v.d.(2ml)
Aluminium oxide assay		0.2 – 0.6 %			0.31 %
Formaldehyde assay		Max. 0.05 %			0.003 %
Thiomersal assay		0.1 mg/ml (0.085 – 0.115)			0.097 mg/ml
Air-tightness		The vials must be closed hermetically			conforms

* The test is carried out as the in-process control during production of antigens

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. 549,V001.



29/08/2024
Mgr. Hana Nezvalová
HEAD of QC, QP