

CERTIFICATE OF ANALYSIS

Product: **BoviBio Respi 4, suspensie injectabilă**

Batch No.: **68 52 26 C**

Expiry: **07.02.2021**

Date of production: **08.02.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Rosy liquid with sediment.		conforms
Content of original package	min. 2 ml, 10 ml, 20 ml, 50 ml, 100 ml		51.4 ml
Sterility	The vaccine must be sterile.		sterile
Inactivation	Every antigen must be inactivated.		conforms
Efficacy	The vaccine must be efficient.		conforms
Identity	The vaccine stimulates the production of specific antibodies against declared antigens.		conforms
pH	6.5 – 7.5		7.5
Bacterial endotoxins	max. 5.72×10^4 EU/vaccination dose (2 ml)		7.81×10^3 IU/v.d.
Aluminium oxide content	0.2 – 0.6 %		0.4 %
Formaldehyde content	max. 0.05 %		0.002 %
Thiomersal content	0.1 mg / ml (0.085 – 0.115)		0.099 mg /ml
Air tightness	The vials must be closed hermetically		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. 190.




23/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP