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CERTIFICATE OF ANALYSIS

Product: **BioBos RCC, suspensie injectabilă**

Batch No.: **045929B**

Expiry: **08/2024**

Date of production: **1.9.2022**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Appearance		An orange, pink to deep pink liquid with a whitish sediment that is dispersed homogenously after shaking.		conforms
Extractable volume		Min. 2 ml, 10 ml, 50 ml, 100 ml		52.2 ml
Air tightness		The vial must be hermetically sealed.		conforms
Sterility		The product must be sterile.		sterile
pH		6.8 – 7.8		7.36
Potency*	E.coli	$1.51 \leq RP \leq 6.00$	$RP \geq 1$	1.88
	BCV	$1.20 \leq RP \leq 2.62$	$RP \geq 1$	1.32
	BRV	$1.22 \leq RP \leq 2.82$	$RP \geq 1$	1.51
Identity*		Identity is confirmed by production of antibodies to declared antigens.		conforms
Aluminium oxide content*		(2.7 – 3.3 mg/ml)		2.957 mg/ml
Thiomersal content*		(0.085 – 0.115 mg/ml)		0.102 mg/ml
Endotoxins assay **		Max. 3.2×10^5 EU/ml		1.27×10^5 EU/ml
Formaldehyde content*		Max. 0.05 %		0.003 %
Quillaja saponin content*		0.08 – 0.2 mg/ml		0.193 mg/ml

*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. 492,V001.



.....05/01/2023
Mgr. Hana Nezvalová
HEAD of QC, QP