



CERTIFICATE OF ANALYSIS

Product: **Biocan Novel R, suspensie injectabilă**

Batch No.: **045430A**

Expiry: **03/2025**

Date of production: **12.4.2023**

Results of analysis:

Tests	Release limits	Shelf – life limits	Results
Appearance	Pink fluid with easily shakeable sediment.		complies
Extractable volume	min. 1 ml; min 10 ml		1.0 ml
Sterility	Vaccine must be sterile.		sterile
Rabies inactivation*	No live virus must be detected.		complies
Rabies identity / potency (serology in mice)	The vaccine stimulates the production of specific neutralizing antibodies.		complies
	The serology response after vaccination has to be significantly higher in comparison to a serology response of standard 2 IU vaccine.		>2 IU p-0.002
pH	6.8 - 7.8		7.5
Aluminium content*	1.8 – 2.2 mg/ml		2.03 mg/ml
Thiomersal content*	0.085 – 0.115 mg/ml		0.091 mg/ml
Airtightness	The glass vial must be hermetically sealed.		complies

* Test is performed as in-process control.

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. 474,V001.

.....07/08/2023
Mgr. Hana Nezvalová
HEAD of QC, QP

