

CERTIFICATE OF ANALYSIS

Product: **NARKAMON BIO, solutie injectabilă, 100 mg/ml**

Batch No.: **725131A**

Expiry: **12/2025**

Date of production: **30.1.2024**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, colourless solution free of mechanical particles.		conforms
Extractable volume	min. 10.0 ml min. 50.0 ml		51 ml
pH of injection solution	4.5 – 5.5		4.9
Ketamine hydrochloride identity	Must comply.		conforms
Ketamine hydrochloride content	109.57 – 121.11 mg/ml		114.15 mg/ml
Impurities			
impurity A	max. 0.5 %		0.0 %
individual unspecified impurity	max. 0.5 %		0.0 %
sum of impurities	max. 1.0 %		0.0 %
Benzethonium chloride identity	Must comply.		conforms
Benzethonium chloride content	0.090 – 0.110 mg/ml		0.098 mg/ml
Disodium edetate identity	Must comply.		conforms
Disodium edetate content	0.090 – 0.110 mg/ml		0.101 mg/ml
Sterility	Must comply.		sterile
Bacterial endotoxins	Max. 25 IU/ml		<25 IU/ml
Airtightness	The vial must be airtightly sealed.		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. 396,V002.



26.2.2024
Mgr. Hana Nezvalová
HEAD of QC, QP