

CERTIFICATE OF ANALYSIS

Product: **SELIVERM 120 mg, soluție spot-on pentru câini L**

Batch No.: **0224C01**

Expiry: **09/2026**

Date of production: **4.10.2024**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	A clear, colourless to yellow or yellow-green solution. The solution is clear like water R. The yellow colour of the solution is not more intense than the colour of the reference solution Y1. The green-yellow colour of the solution is not more intense than the colour of the reference solution GY1.		complies
Microbiological quality:			
TAMC	< 10 ² (CFU/g or CFU/ml)		<10 CFU/ml
TYMC	< 10 ¹ (CFU/g or CFU/ml)		<10 CFU/ml
<i>Staphylococcus aureus</i>	absent (in 1 g or 1 ml)		absent
<i>Pseudomonas aeruginosa</i>	absent (in 1 g or 1 ml)		absent
Water content	Max. 2.0 %		0.23 %
Density	0.8370 – 0.8600 g/cm ³		0.8483 g/cm ³
Refractive index	1.37 – 1.43		1.401
Selamectin identity test	RT and UV spectrum match with standard		complies
Selamectin assay	114.00 – 126.00 mg/tube	111.60 – 126.00 mg/tube	121.075 mg/tube
Butylhydroxytoluene identity test	Rt and UV spectrum match with standard		complies
BHT assay	0.72 – 0.88 mg/ml	Max. 0.88 mg/ml	0.826 mg/ml
Purity test	Impurity A – max. 2.0 %		0.11 %
	Impurity B – max. 2.0 %		0.12 %
	Impurity C – max. 1.5 %		ND
	Impurity D – max. 1.5 %		ND
	Any individual undefined impurity - max. 1.0 %		<1.0 %
	Sum of impurities – max. 4.0 %		0.58 %
Uniformity of dosage units (Weight variability)	Must comply.		complies
Average extractable volume	0.9000 - 1.1000 ml		1.000 ml

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. 556c,V001.



17/12/2024
Mgr. Hana Nezvalová
HEAD of QC, QP