

CERTIFICATE OF ANALYSIS

Product: **OVIVERM 25 mg/ml, suspensie orală**Batch No.: **525633A**Expiry: **05/2028**Date of production: **6.6.2026**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White suspension.		conforms
Microbiological quality:			
TAMC	$< 10^2$ (CFU/g or CFU/ml)		< 10 CFU/g
TYMC	$< 10^1$ (CFU/g or CFU/ml)		< 10 CFU/g
<i>Escherichia coli</i>	absent (in 1 g or 1 ml)		absent
Density	0.9850 – 1.0450 g/cm ³		1.0142 g/cm ³
pH	4.50 – 5.70		5.04
Praziquantel identity	Rt and UV spectrum match with standard		conforms
Praziquantel content	23.75 – 26.25 mg/ml		24.921 mg/ml
Sodium benzoate identity	Rt and UV spectrum match with standard		conforms
Sodium benzoate content	1.80 – 2.20 mg/ml		1.864 mg/ml
Sodium propionate identity	Rt and UV spectrum match with standard		conforms
Sodium propionate content	1.80 – 2.20 mg/ml		1.915 mg/ml
Purity test	Praziquantel impurities: Impurity A – max. 0.5 % Impurity B – max. 0.5 % Any individual undefined impurity - max. 1.0 % Sum of impurities – max. 1.5 %		0.07 % 0.00 % ND 0.07 %
Particle size	Min. 10% of particles (Dv_{10}) $\leq 5 \mu\text{m}$ Min. 50% of particles (Dv_{50}) $\leq 10 \mu\text{m}$ Min. 90% of particles (Dv_{90}) $\leq 30 \mu\text{m}$		conforms conforms conforms
Viscosity	100 - 550 mPas		275.0 mPas
Dispersibility	Must pass the test.		conforms
Sedimentation	Must pass the test.		conforms
Package extractable volume	min. 950 ml		985.0 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. 566, V001.



V.2.21 08/09/2026

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HEAD of QC, QP