

CERTIFICATE OF ANALYSIS

Product: **EQUIMOXIN 18,92 mg/g, gel oral**

Batch No.: **225130A**

Expiry: **12/2025**

Date of production: **11.1.2023**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Translucent, clear to yellow gel.		conforms
Package extractable volume	Min. 14.8 g		15.1 g
pH	6.5 – 7.0		6.7
Loss on drying	(68.2 – 75.3) %		70.20 %
Microbiological quality	Must comply. TAMC (CFU/g or CFU/ml) 10^2 TYMC (CFU/g or CFU/ml) 10^1 Absence of <i>Escherichia coli</i> (in 1 g)		conforms <10 CFU/g <10 CFU/g absent
Density (at 25 °C)	(1.036 – 1.078) g.cm ⁻³		1.037 g.cm ⁻³
Identity – proof of moxidectin	Must comply.		conforms
Moxidectin content	(17.97 – 20.81) mg/g	(17.05 – 20.81) mg/g	18.65 mg/g
Identity test – proof of benzyl alcohol	Must comply.		conforms
Benzyl alcohol content	(34.1 – 41.6) mg/g	(31.8 – 41.6) mg/g	36.48 mg/g
Identity test – proof of disodium edetate	Must comply.		conforms
Disodium edetate content	Max. 0.265 mg/g		0.256 mg/g
Purity tests			
Moxidectin impurities			
- impurity A, C and G	max. 1.5 %		<1.5 %
- sum of impurities E + F	max. 1.7 %		0.2 %
- impurity D	max. 2.5 %		0.0 %
impurities B, H, I, J, K and any individual undefined impurity	max. 1.0 %		<1.0 %
- sum of impurities	max. 8.0 %		1.6 %
Injectability	Must comply.		conforms
Viscosity	8000 – 13000 mPa.s		10 625 mPa.s
Uniformity of mass of delivered doses from multidose containers	Must comply.		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. 481,V001.



27/02/2023
Mgr. Hana Nezvalová
HEAD of QC, QP