

CERTIFICATE OF ANALYSIS

Product: **CANIVERM, pastă orală**

Batch No.: **76 61 26 A**

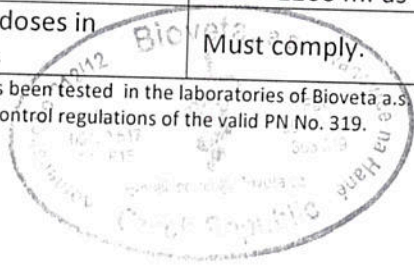
Expiry: **21.05.2021**

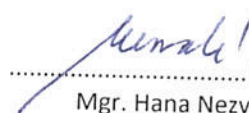
Date of production: **22.11.2019**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Appearance		Yellow, homogeneous paste.		complies
Package usable volume		min. 4.0 ml, min. 10.0 ml		10.30 ml
Water content		max. 0.3 %		0.01 %
Microbiological safety		Must comply. TAMC (CFU/g): 10 ³ TYMC (CFU/g): 10 ² <i>Escherichia coli</i> : absent		complies
Density		1.010 – 1.070 g/cm ³		1.034 g/cm ³
Identity of fenbendazole		Must comply.		complies
Content of fenbendazole		(71.25 – 78.75) mg/ml		74.79 mg/ml
Identity of pyrantel embonate		Must comply.		complies
Content of pyrantel embonate		(68.40 – 75.60) mg/ml		73.05 mg/ml
Identity of praziquantel		Must comply.		complies
Content of praziquantel		(23.75 – 26.25) mg/ml		24.40 mg/ml
Identity of bulylhydroxyanisole		Must comply. Compliance of RT of reference standard and sample Compliance of fluorescent spectra of sample and standard		complies
Content of bulylhydroxyanisole		(0.18 – 0.22) mg/ml		0.218 mg/ml
Purity tests:				
Fenbendazole impurities:				
- content of oxfendazole		max. 1.0 %		0.00 %
- any individual unidentified impurity		max. 1.0 %		ND
- sum of impurities		max. 3.0 %		0.00 %
Pyrantel embonate impurities:				
- any individual unidentified impurity		max. 1.0 %		ND
- sum of impurities		max. 3.0 %		0.00 %
Praziquantel impurities:				
- any individual unidentified impurity		max. 1.0 %		<1.0 %
- sum of impurities		max. 3.0 %		1.28 %
Particle size		min. 95 % of particles < 25 µm		100 %
Injectability		Must comply.		complies
Viscosity		800 – 1200 mPa.s		927 mPa.s
Mass uniformity of doses in multidose containers		Must comply.		complies

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. 319.




 16/01/2020
 Mgr. Hana Nezvalová
 HEAD of QC,QP