

CERTIFICATE OF ANALYSIS

Product: **CANIVERM, pastă orală**

Batch No.: **75 61 26 A**

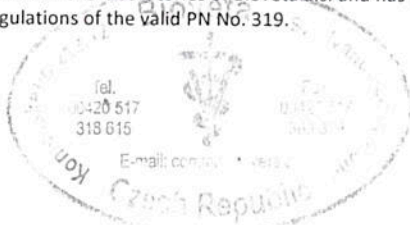
Expiry: **20.05.2021**

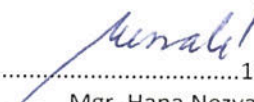
Date of production: **21.11.2019**

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		4.30 ml
Water content	max. 0.3 %		0.02 %
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		1.037 g/cm ³
Identity of fenbendazole	Must comply.		complies
Content of fenbendazole	(71.25 – 78.75) mg/ml		74.29 mg/ml
Identity of pyrantel embonate	Must comply.		complies
Content of pyrantel embonate	(68.40 – 75.60) mg/ml		72.73 mg/ml
Identity of praziquantel	Must comply.		complies
Content of praziquantel	(23.75 – 26.25) mg/ml		24.59 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		0.210 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 %		1.21 %
Particle size	min. 95 % of particles < 25 µm		complies
Injectability	Must comply.		complies
Viscosity	800 – 1200 mPa.s		860 mPa.s
Mass uniforminty 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