

CERTIFICATE OF ANALYSIS

Product: **CANIVERM comprimate á 0,175 g**

Batch No.: **B009-03**

Expiry: **12/2023**

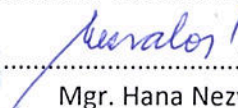
Date of production: **26.1.2022**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Round, yellowish tablets with small spots and a dividing line on one side.		conforms
Content of original package	2 x 1 tbl., 6 x 1 tbl., 100 x 1 tbl.		conforms
Microbiological quality			
- TAMC	10 ⁴ CFU/g		<10 CFU/g
- TYMC	10 ² CFU/g		<10 CFU/g
- Bile tolerant gram-negative bacteria	Max. 10 ² CFU v 1g		<10 CFU v 1g
- Absence of Salmonella	Absence in 10 g		absent
- Absence of Escherichia coli	Absence in 1 g		absent
- Absence of Staphylococcus aureus	Absence in 1 g		absent
Content of fenbendazole	35.625 – 39.375 mg/0.175 g		38.077 mg/0.175 g
Fenbendazole identity	Must comply.		conforms
Content of pyrantel embonate	34.2 – 37.8 mg/0.175 g		36.19 mg/0.175 g
Pyrantel identity	Must comply.		conforms
Content of praziquantel	11.875 – 13.125 mg/0.175 g		12.541 mg/0.175 g
Praziquantel identity	Must comply.		conforms
Weight uniformity of tablets	0.166 – 0.184 g		0.176 g
Impurities of fenbendazole			
- content of oxfendazole	Max. 1.0 %		0.1 %
- any individual unidentified impurity	Max. 1.0 %		0.3 %
- sum of impurities	Max. 3.0 %		0.6 %
Impurities of pyrantel embonate			
- any individual unidentified impurity	Max. 1.0 %		0.0 %
- sum of impurities	Max. 3.0 %		0.0 %
Impurities of praziquantel			
- any individual unidentified impurity	Max. 1.0 %		0.0 %
- sum of impurities	Max. 3.0 %		0.0 %
Determination of tablet strength	Min. 35 N		59 N
Tablet disintegration	Max. 15 min.		13 min.
Determination of abrasion of uncoated tablets	Max. 1.0 %		0.10 %

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. 317,V003.




25/4/2022
 Mgr. Hana Nezvalová
 HEAD of QC, QP