

CERTIFICATE OF ANALYSIS

Product: **EQUIVERM DUO, pastă orală**
Batch No.: **94 51 26 A**
Expiry: **08.01.2021**
Date of production: **09.01.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Green paste with a characteristic odour of apples and cinnamon.		complies
Package usable volume	min. 7.0 ml		7.5 ml
Water content (KF)	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 < 10 CFU/g < 10 CFU/g absent
Density	1.000 – 1.050 g/cm ³		1.002 g/cm ³
Ivermectin identity test	Must comply.		complies
Determination of ivermectin content	(19.0 – 21.0) mg/ml		20.6 mg/ml
Praziquantel identity test	Must comply.		complies
Determination of praziquantel content	(95.0 – 105.0) mg/ml		100.9 mg/ml
Butylhydroxyanisole identity test	Must comply.		complies
Determination of butylhydroxyanisole content	(0.18 – 0.22) mg/ml	0.21 mg/ml	0.22 mg/ml
Purity tests			
Ivermectin impurities			
- impurities with a relative retention of 1.0-1.2	max. 2.5 %		0.3 %/ 0.7 %
- any individual undefined impurity	max. 1.0 %		Complies
- sum of impurities	max. 5.0 %		1.7 %
Praziquantel impurities			
- any individual undefined impurity	max. 1.0 %		complies
- sum of impurities	max. 2.0 %		0.5 %
Particle size	min. 95 % of particles ≤ 30 µm		complies
Injectability	Must comply.		complies
Viscosity	800 – 1600 mPa.s		1 595 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. 102,spec.01.



02/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP