

CERTIFICATE OF ANALYSIS

Product: **FIPRIN 67 mg, soluție spot-on pentru câini S**

Batch No.: **49 19 B01**

Expiry: **29.10.2021**

Date of production: **30.10.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, yellow to yellow-green solution. Solution is as clear as water R. Solution is not more intensely yellow-coloured than reference solution Y2. Solution is not more intensely greenish-yellow-coloured than reference solution GY 1.		complies
Microbiological safety	Product must be safe.		complies
Water content	max. 1.5 %	max 5.0 %	0.74 %
Density	(1.018 – 1.038) g/cm ³		1.022 g/cm ³
Index of refraction	1.40 – 1.48		1.44
Identity of fipronil	Must be proved.		complies
Fipronil content	(63.65 – 70.35) mg/tube		69.13 mg/tube
Butylhydroxyanisole identity test	Must be proved.		complies
Determination of butylhydroxyanisole content	(0.18 – 0.22) mg/ml		0.191 mg/ml
Butylhydroxytoluene identity test	Must be proved.		complies
Determination of butylhydroxytoluene content	0.09 – 0.11 mg/ml	0.08 - 0.11 mg/ml	0.09 mg/ml
Purity tests	Fipronil impurities impurity A – max. 1.0 % impurity B – max. 1.0 % any individual undefined impurity – max. 1.0 %		0.14 % 0.22 % <1.0 %
	sum of impurities – 2.0 %	sum of impurities – 4.0 %	1.11 %
Mass uniformity of doses in multidose containers	Must comply.		complies
The average volume of usable	Y ± 5% (Y = theoretical value of the desired extractable volume)		0.6999 ml

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. 112a.




26/11/2019
 Mgr. Hana Nezvalová
 HEAD of QC, QP