

CERTIFICATE OF ANALYSIS

Product: **FIPRIN 402 mg, soluție spot-on pentru câini XL**

Batch No.: **22 19 A01**

Expiry: **07.03.2021**

Date of production: **08.03.2019**

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 3.0 %	0.632 %
Density	(1.018 – 1.038) g/cm ³		1.0230 g/cm ³
Index of refraction	1.40 – 1.48		1.435
Identity of fipronil	Must be proved.		complies
Fipronil content	(381.90 – 422.10) mg/tube		387.57 mg/tube
Butylhydroxyanisole identity test	Must be proved.		complies
Determination of butylhydroxyanisole content	(0.18 – 0.22) mg/ml		0.202 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	0.10 mg/ml
Purity tests	Fipronil impurities		
	impurity A – max. 1.0 %		0.11 %
	impurity B – max. 1.0 %		0.26 %
	any individual undefined impurity – max. 1.0 %		<1.0 %
	sum of impurities – 2.0 %	sum of impurities – 4.0 %	0.76 %
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)		3.846 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. 112d.



Hana
07/05/2019
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HEAD of QC, QP