

CERTIFICATE OF ANALYSIS
No. 555/31.07.2024

MILBENIN 12.5 mg/125 mg chewable tablets for dogs

Batch no: 30V002

Manufacturing date: 07.2024

Expiry date: 06.2026

Analysis performed in conformity with Product Specification (ST-30AUV-2024-04-EN-P)

TESTS	REQUIREMENTS	RESULTS
Aspect, colour	Round, white or almost white, evenly distributed, brownish-pigmented tablets, with beveled edges; diameter: approx. 12 mm	Complies
Odour	Characteristic	Complies
Average mass, mg	570.0 – 630.0 (600.0 ± 5 %)	600.5
Identification		
A. by retention times	The 3 principal peaks (milbemycin oxime A ₃ , milbemycin oxime A ₄ , and praziquantel) in the chromatogram obtained with the test solution are similar in retention time and size to the 3 principal peaks in the chromatogram obtained with reference solution (a). The UV spectra of the 3 principal peaks (milbemycin oxime A ₃ , milbemycin oxime A ₄ , and praziquantel) in the DAD chromatogram obtained with the test solution are similar to the UV spectra of the 3 principal peaks in the DAD chromatogram obtained with reference solution (a).	Complies
- milbemycin oxime A ₃		
- milbemycin oxime A ₄		
- praziquantel		
B. by UV spectra		Complies
- milbemycin oxime A ₃		
- milbemycin oxime A ₄		
- praziquantel		
Water, %	max. 6.0	5.21
Dissolution		
- milbemycin oxime (A ₃ + A ₄), % after 60 min.	min. 75 (Q)	96.76
- praziquantel, % after 60 min.	min. 75 (Q)	96.94
Assay		
- milbemycin oxime (A ₃ + A ₄), mg/tablet	11.875 – 13.125 (12.500 ± 5 %)	12.430
- praziquantel, mg/tablet	118.75 – 131.25 (125.00 ± 5 %)	124.28
Uniformity of dosage units (Content uniformity)		
Acceptance value (AV)		
- milbemycin oxime (A ₃ + A ₄)	max. 15	3.5
- praziquantel	max. 15	3.6

TESTS	REQUIREMENTS	RESULTS
Related substances (HPLC)		
Milbemycin oxime		ND
- impurity G, %	max. 0.2	ND
- impurity E, %	max. 0.7	ND
- impurity H, %	max. 0.5	ND
- impurity I, %	max. 0.5	ND
- any other individual impurity, %	max. 0.3	0.12
- total impurities, %	max. 3.5	0.12
Praziquantel		0.06
- impurity A, %	max. 0.2	ND
- impurity B, %	max. 0.2	ND
- unspecified impurities, %	max. 0.10	ND
- total	max. 0.5	0.06
Microbiological quality*		
- total aerobic microbial count, CFU/g	max. 10^3	*)
- total yeasts and moulds count, CFU/g	max. 10^2	*)
- Escherichia coli, CFU/g	absence	*)

*) The test is performed by 10 to 10 batches

Conclusions: The analyzed product is Milbenin 12.5 mg/125 mg chewable tablets for dogs, which corresponds with the requirements of the Product Specification.

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