



KRKA-FARMA d.o.o.
Site Jastrebarsko
Quality management

Jastrebarsko, 04.12.2023.

CERTIFICATE OF ANALYSIS

Code: 7G5330

Product: MILPRAZON DOGS 2,5 MG/25 MG tablets for veterinary use Packaging: 48 tablets

Batch No: H15201

Batch number semiproduct: H15042

Manuf. Date: 10 2023

Exp. Date: 10 2026

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TEST	RESULTS	SPECIFICATION
Appearance	Complies	Yellowish-white with brown spots, oval, biconvex tablets scored on one side.
Uniformity of mass of subdivided tablets	/	Not more than one of 30 masses is outside the limits of 85% - 115% of the average mass and none is outside the limits of 75% - 125% of the average mass.
Water	2.9%	Not more than 4.0 %.
Uniformity of dosage units- content uniformity of milbemycin oxime	7.0%	Acceptance value (AV): not more than 15.0 %.
Uniformity of dosage units- content uniformity of praziquantel	6.9 %	Acceptance value (AV): not more than 15.0 %.
Identification of milbemycin oxime: - HPLC - TLC	Complies Complies	Assay is identification at the same time. Complies with the test in the analytical procedure.
Identification of praziquantel - HPLC - TLC	Complies Complies	Assay is identification at the same time. Complies with the test in the analytical procedure.
Related substances of milbemycin oxime: - impurity G - other individual - total (excluding impurity G)	$\leq 0.3\%$ $\leq 0.3\%$ $\leq 0.3\%$	Not more than 2.0% Not more than 0.5% Not more than 3.5%

Qualified Person for batch release:
Maja Staroveški, MPharm

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