



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

Jastrebarsko, 06.10.2023,

CERTIFICATE OF ANALYSIS

Code: 7G5331

Product: MILPRAZON 12,5 MG/125 MG tablets for dogs

Packaging: 48 tablets

Batch No: H14901

Batch no semiproduct: H14830

Manuf. Date: 07 2023

Exp. Date: 07 2026

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TEST	RESULTS	SPECIFICATION
Appearance	Complies	Yellowish-white with brown spots, round, slightly biconvex tablets.
Water	3.1%	Not more than 4.0%
Uniformity of dosage units - content uniformity of milbemycin oxime	2.0%	Acceptance value (AV): not more than 15.0%.
Uniformity of dosage units - Content uniformity of praziquantel	2.8%	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 test procedure
Identification of praziquantel - HPLC - TLC	Complies Complies	Assay is identification at the same time Complies with the test in the test procedure
Content of milbemycin oxime	12.3 mg/tbl (98%)	11.9 mg – 13.1 mg/tablet (95% - 105% of the stated amount)
Content of praziquantel	123.1 mg/tbl (99%)	118.8 mg – 131.3 mg/tablet (95% - 105% of the stated amount)
Related substances of milbemycin oxime: - impurity G - other individual - total (excluding impurity G)	≤ 0.3% ≤ 0.3% ≤ 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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