KRKA

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

Jastrebarsko, 24.06.2024.

CERTIFICATE OF ANALYSIS

Code: **7G5331**

Product: **Milprazon® 12,5 mg/125 mg tablets for dogs** Packaging: 48 tablets

Batch No: **H15845** Batch number semiproduct: H15396

Manuf. Date: 01 2024

Exp. Date: 01 2027

TEST	RESULTS	SPECIFICATION
Appearance	Complies	Yellowish-white with brown spots, round, slightly biconvex tablets.
Water	3.0%	Not more than 4.0%
Uniformity of dosage units – content uniformity of milbemycin oxime	1.6%	Acceptance value (AV): not more than 15.0%.
Uniformity of dosage units – content uniformity of praziquantel	2.0%	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.
Related substances of milbemycin oxime: - impurity G - other individual - total (excluding impurity G)	 ≤ 0.30% ≤ 0.30% ≤ 0.30%	 Not more than 2.0% Not more than 0.5% Not more than 3.5%
Related substances of praziquantel: - individual - total	 ≤ 0.30% ≤ 0.30%	 Not more than 0.5% Not more than 1.0%
Dissolution of milbemycin oxime	98-102%	Not less than 75% (Q) of the stated amount in 45 minutes.
Dissolution of praziquantel	98-102%	Not less than 75% (Q) of the stated amount in 45 minutes.
Content of milbemycin oxime	12.6 mg/tbl (101%)	11.9 mg – 13.1 mg/tablet (95% - 105% of the stated amount)

KRKA-FARMA d.o.o. HR 10 ZAGREB, Radnička cesta 48

Qualified Person for Batch Release:
Maja Staroveški, MPharm
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TEST	RESULTS	SPECIFICATION
Content of praziquantel	126.0 mg/tbl (101%)	118.8 mg – 131.3 mg/tablet (95% - 105% of the stated amount)
[1)]**Microbiological quality:** TAMC: TYMC: E.coli:	 / / /	 Max. 1000 CFU/g Max. 100 CFU/g Absent in 1 g

[1)] Testing is performed according to the programme:
Initially 10 consecutive batches are tested.
a) If the results comply continue by testing at least one batch annually as long as the results comply with the requirements for microbial quality.
b) In case of failure, each batch is tested until 3 consecutive batches comply with the requirements. The testing described under item a) is carried out.

KRKA-FARMA d.o.o. 12 ZAGREB, Radnička cesta 48

Qualified Person for Batch Release:
Maja Staroveški, MPharm
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