KRKA

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

Jastrebarsko, 09.07.2024.

CERTIFICATE OF ANALYSIS

Code: 7F5859

Product: **Milprazon® 16 mg/40 mg film-coated tablets for cats** Packaging: 48 tablets

Batch No: **H15875** Batch number semiproduct: H15719

Manuf. Date: 04 2024

Exp. Date: 04 2027

TEST	RESULTS	SPECIFICATION
Appearance	Complies	Brown red, oval, biconvex film-coated tablets with score line on one side.
[1]Uniformity of mass of subdivided tablets	/	Not more than one of 30 masses is ouside the limits of 85% - 115% of the average mass and none is outside the limits of 75% - 125% of the average mass.
Water content	2.8%	Not more than 6.0%
Uniformity of dosage units – content uniformity of milbemycin oxime	2.3%	Acceptance value (AV): not more than 15.0%.
Uniformity of dosage units – content uniformity of praziquantel	2.7%	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	96-98%	Not less than 75% (Q) of the stated amount in 45 minutes.
Dissolution of praziquantel	97-98%	Not less than 75% (Q) of the stated amount in 45 minutes.

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

Qualified Person for Batch Release:
Maja Staroveški, MPharm
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TEST	RESULTS	SPECIFICATION
Content of milbemycin oxime	15.9 mg/tbl (99%)	15.2 mg – 16.8 mg/tablet (95% - 105% of the stated amount)
Content of praziquantel	38.9 mg/tbl (97%)	38.0 mg – 42.0 mg/tablet (95% - 105% of the stated amount)
[1)] **Microbiological quality:**		
TAMC:	/	Max. 1000 CFU/g
TYMC:	/	Max. 100 CFU/g
E.coli:	/	Absent in 1 g

[1)] Tested according to the programme:
Initially ten 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.
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.

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