



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

Jastrebarsko, 8.7.2022.

### CERTIFICATE OF ANALYSIS

Code: 7F5864

Product: MILPRAZON® film-coated tablets 4 mg/10 mg Packaging: 48 tablets

Batch No: H13515

Batch no semiproduct: H13411

Manuf. Date: 05 2022

Exp. Date: 05 2025

Page 1 of 2

TEST	RESULTS	SPECIFICATION
Appearance	Complies	Brown yellow, oval, biconvex film-coated tablets with score line on one side.
<sup>1</sup> 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 content	4.9%	Not more than 6.0 %.
Uniformity of dosage units- content uniformity of milbemycin oxime	3.6%	Acceptance value (AV): not more than 15.0 %.
Uniformity of dosage units- content uniformity of praziquantel	3.4%	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)	$\leq 0.3\%$ $\leq 0.3\%$ $\leq 0.3\%$	Not more than 2.0% Not more than 0.5% Not more than 3.5%

Qualified Person for batch release:  
Nikoljina Miovec, MPharm

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