

**CERTIFICATE OF ANALYSIS**

Code: 7F5859

Product: MILPRAZON film-coated tablets 16 mg/40 mg Packaging: 48 tablets

Batch No: H15242

Batch no semiproduct: H14860

Manuf. Date: 08 2023

Exp. Date: 08 2026

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TEST	RESULTS	SPECIFICATION
Appearance	Complies	Brown red, oval, biconvex film-coated tablets with score line on one side.
<sup>m</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	2.8%	Not more than 6.0 %.
Uniformity of dosage units-content uniformity of milbemycin oxime	2.8%	Acceptance value (AV): not more than 15.0 %.
Uniformity of dosage units-content uniformity of praziquantel	2.3%	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)	≤ 0.3% ≤ 0.3% ≤ 0.3%	Not more than 2.0% Not more than 0.5% Not more than 3.5%

