



KRKA-FARMA d.o.o.  
QUALITY MANAGEMENT  
V. Hojčevca 20/E  
10450 Jastrebarsko, Croatia  
Tel: +385 1 531 21 01  
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## BATCH CERTIFICATE

Name of the Product: 7H9474 MILPRAZON DOGS 2,5 mg/25 mg tablets for veterinary use	
Batch No. of the Product: H17221	
Date of manufacture: 03.2025	Expiry date: 03.2028
Dosage form: tablet	
Strength/Potency: Milbemycin/Praziquantel 2.5 mg/25 mg	
Package type: Blister	Package size: 48
Batch No. bulk: H16831	
Importing country - Marketing Authorisation No.: EE - 1876; PL - 239915; SK - 96/076/DC/14-S	
Name and address of manufacturing site for bulk: KRKA-FARMA d.o.o. V. Hojčevca 20/E 10450 Jastrebarsko, Croatia	Manufacturing Authorisation No: UP/I-322-05/18-01/446; 525-10/0268-18-17
	GMP certificate No: UP/I-530-10/22-03/22;361-13-08/243-23-12
Name and address of manufacturing site for finished product: KRKA-FARMA d.o.o. V. Hojčevca 20/E 10450 Jastrebarsko, Croatia	Manufacturing Authorisation No: UP/I-322-05/18-01/446; 525-10/0268-18-17
	GMP certificate No: UP/I-530-10/22-03/22;361-13-08/243-23-12
Name and address of quality control: KRKA-FARMA d.o.o. V. Hojčevca 20/E 10450 Jastrebarsko, Croatia	Manufacturing Authorisation No: UP/I-322-05/18-01/446; 525-10/0268-18-17
	GMP certificate No: UP/I-530-10/22-03/22;361-13-08/243-23-12

Quantity of Batch: 5.472 PC

Comments/remarks/  
Certification statement:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The batch is released.

Date of signature:  
23.07.2025

Qualified Person certifying the Batch:  
Maja Staroveški

  
KRKA  
tovarna zdravil, d.d.  
Nova mesto

## BATCH CERTIFICATE

Name of the Product: 7H9474 MILPRAZON DOGS 2,5 mg/25 mg tablets for veterinary use	
Batch No. of the Product: H17221	
Date of manufacture: 03.2025	Expiry date: 03.2028
According to Specification: DPSPEC005884_6	

Characteristic	Specification	Results
Appearance	Yellowish-white with brown spots, oval, biconvex tablets scored on one side.	Complies
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.	*1
Water	Max. 4.0 %	2.9
Uniformity of dosage units- content uniformity of milbemycin oxime-AV	Max. 15.0 %	2.7
Uniformity of dosage units- content uniformity of praziquantel-AV	Max. 15.0 %	3.4
Identification of milbemycin oxime (HPLC)	Assay is identification at the same time.	Complies
Identification of milbemycin oxime (TLC)	Complies with the test in the analytical procedure.	Complies
Identification of praziquantel (HPLC)	Assay is identification at the same time.	Complies
Identification of praziquantel (TLC)	Complies with the test in the analytical procedure.	Complies
Related substances of milbemycin oxime-impurity G	Max. 2.0 %	<= 0.30
Related substances of milbemycin oxime-other individual	Max. 0.5 %	<= 0.30
Related substances of milbemycin oxime-total (excluding impurity G)	Max. 3.5 %	<= 0.30
Related substances of praziquantel-individual	Max. 0.5 %	<= 0.30
Related substances of praziquantel-total	Max. 1.0 %	<= 0.30
Dissolution of milbemycin oxime 75%(Q)	Min. 80 % of st.am in 45 min	96 -101
Dissolution of praziquantel 75%(Q)	Min. 80 % of st.am in 45 min	96 -102
Content of milbemycin oxime	2.38 - 2.63 mg/tab.	2.53
Content of milbemycin oxime	95 - 105 % of stated amount	101
Content of praziquantel	23.6 - 26.3 mg/tab.	25.5
Content of praziquantel	95 - 105 % of stated amount	102
Microbial quality - TAMC	Max. 1000 CFU/g	*2
Microbial quality - TYMC	Max. 100 CFU/g	*2
Microbiological quality - Escherichia coli	Absent in 1 g	*2

\*1 First ten production batches are tested and than at least one batch annually.  
 \*2 First ten production batches are tested and than at least one batch annually.