KRKA, d. d., Novo mesto
QUALITY MANAGEMENT
Šmarješka cesta 6
8501 Novo mesto
Slovenia
Tel: +386 7 3312 111
Mail: info@krka.biz

BATCH CERTIFICATE

Name of the Product: **7D0139 PRINOCATE CATS 80 mg/8 mg spot on solution for veterinary use**	
Batch No. of the Product: **Z98017**	
Date of manufacture: **12.2023**	Expiry date: **12.2025**
Dosage form: **spot-on solution**	
Strength/Potency: **Imidacloprid/Moxidectin 100 mg/10 mg/ml**	
Package type: **Tube/Bag**	Package size: **3X0.8 ml**
Batch No. bulk: **Z98014**	
Importing country - Marketing Authorisation No.: **EE - 2217; PL - 2941/20; SI - DC/V/0690/002; SK - 96/067/DC/19-S**	
Name and address of manufacturing site for bulk: **KRKA, tovarna zdravil, d.d., Novo mesto** **Povhova ulica 5** **Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6** GMP certificate No: **401-6/2021-3**
Name and address of manufacturing site for finished product: **KRKA, tovarna zdravil, d.d., Novo mesto** **Povhova ulica 5** **Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6** GMP certificate No: **401-6/2021-3**
Name and address of quality control: **KRKA, d.d., Novo mesto** **Šmarješka cesta 6** **Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6** GMP certificate No: **401-5/2021-5**

Quantity of Batch: **7.469 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:
29.02.2024

Qualified Person certifying the Batch:
Milena Žigante

KRKA,
tovarna zdravil, d.d.,
Novo mesto

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Batch No. of the Product: **Z98017**

Date of manufacture: **12.2023** Expiry date: **12.2025**

According to Specification: **DPSPEC007987/3**

Characteristic	Specification	Results	
Appearance	Clear, slightly yellow to yellow or to brownish yellow solution.	Complies	
Seal integrity	Must comply with the test.	Complies	
Density	1.095 - 1.101 g/ml	1.098	
Clarity and degree of opalescence of liquids	The solution must be clear	Complies	
Degree of coloration of liquids	The solution is not more intensively coloured than reference solution BY4 or Y4.	Complies	
Water	Max. 2.0 %	0.1	*1
Uniformity of dosage units-mass variation of imidacloprid; AV	Max. 15.0 %	3.6	
Uniformity of dosage units-mass variation of moxidectin; AV	Max. 15.0 %	3.6	
Related substances of imidacloprid - individual	Max. 0.5 %	<= 0.30	
Related substances of imidacloprid - total	Max. 1.5 %	<= 0.30	
Related substances of moxidectin - 23-keto-nemadectin	Max. 0.5 %	<= 0.30	
Related substances of moxidectin - other individual	Max. 0.5 %	0.3	
Related substances of moxidectin - total	Max. 2.0 %	0.3	
Identification of imidacloprid - HPLC	Assay is at the same time identification.	Complies	
Identification of imidacloprid - TLC	The lower main spot in the chromatogram of sample solution corresponds in approximate Rf value and approximate size to the main spot in the chromatogram of standard solution 1.	Complies	
Identification of moxidectin - HPLC	Assay is at the same time identification.	Complies	
Identification of moxidectin - TLC	The higher main spot in the chromatogram of sample solution corresponds in approximate Rf value and approximate size to the main spot in the chromatogram of standard solution 2.	Complies	
Identification of butylhydroxytoluene	Assay is at the same time identification.	Complies	
Content of butylhidroxytoluene	93 - 116 % of stated amount	103	
Content of imidacloprid (mg/pipette) (0,8ml)	76.0 - 84.0 mg/pipette	80.7	
Content of moxidectin (mg/pipette) (0,8ml)	7.60 - 8.40 mg/pipette	8.05	
Microbiological quality - Staphylococcus aureus	Absent in 1 ml	Complies	*2
Microbiological quality - Pseudomonas aeruginosa	Absent in 1 ml	Complies	*2
Microbial quality - TAMC	Max. 100 CFU/ml	< 10	*2
Microbial quality - TYMC	Max. 10 CFU/ml	< 10	*2

*1 Testing not performed on every batch (monitoring programa- at least one batch per year).
*2 First three production batches are tested and than every 10-th batch or at least one batch annually.

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It has been created automatically by the validated SAP.

Date: 31.07.2024