



KRKA, d. d., Novo mesto
QUALITY MANAGEMENT
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BATCH CERTIFICATE

Name of the Product: 7D0137 PRINOCATE CATS 40 mg/4 mg spot on solution for veterinary use	
Batch No. of the Product: Z98016	
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: 3X0.4 ml
Batch No. bulk: Z98014	
Importing country - Marketing Authorisation No.: EE - 2216; PL - 2939/20; SI - DCN/0690/001; SK - 96/066/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: **14.578 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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According to Specification: DPSPEC007986/3	

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 %	3.4	
Uniformity of dosage units-mass variation of moxidectin; AV	Max. 15.0 %	3.4	
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 butylhydroxytoluene	93 - 116 % of stated amount	103	
Content of imidacloprid (mg/pipette) (0,4ml)	38.0 - 42.0 mg/pipette	40.3	
Content of moxidectin (mg/pipette) (0,4ml)	3.80 - 4.20 mg/pipette	4.02	
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 programme- at least one batch per year).

*2 First three production batches are tested and then every 10-th batch or at least one batch annually.