



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

Name of the Product: 7D0138 PRINOCATE DOGS 250 mg/62,5 mg spot on solution for veterinary use	
Batch No. of the Product: Z98183	
Date of manufacture: 01.2024	Expiry date: 01.2026
Dosage form: spot-on solution	
Strength/Potency: Imidacloprid/Moxidectin 100 mg/25 mg/ml	
Package type: Tube/Bag	Package size: 3X2.5 ml
Batch No. bulk: Z98179	
Importing country - Marketing Authorisation No.: EE - 2220; PL - 2943/20; SI - DCN/0690/005; SK - 96/070/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: **2.376 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: DPSPEC007984_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	1.099
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
Uniformity of dosage units-mass variation of imidacloprid; AV	Max. 15.0 %	1.4
Uniformity of dosage units-mass variation of moxidectin; AV	Max. 15.0 %	1.4
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
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
Content of butylhydroxytoluene	96 - 126 % of stated amount	112
Content of imidacloprid (mg/pipette) (2,5ml)	238 - 263 mg/pipette	254
Content of moxidectin (mg/pipette) (2,5ml)	59.4 - 65.6 mg/pipette	63.3
Microbial quality - TAMC	Max. 100 CFU/ml	< 10
Microbial quality - TYMC	Max. 10 CFU/ml	< 10
Microbiological quality - Staphylococcus aureus	Absent in 1 ml	Complies
Microbiological quality - Pseudomonas aeruginosa	Absent in 1 ml	Complies

*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.