Certificate of Compliance

KRKA, d.d., Novo mesto

Date: 16.03.2020

Name of Product: **7A1432 DEHINEL PLUS FLAVOUR tablets for veterinary use**	
Dosage form: **tablet**	Package size: **10**
Strength/Potency (amount per unit dose): **150 mg/144 mg/50 mg**	
Batch No. final product: **SE6944**	Customer's batch No.:
Batch No. bulk: **SE6061**	-
Date of manufacture: **03.2019**	Expiry date: **03.2022**
Importing country - Marketing Authorisation No.: **RO - 160363**	
Name and address of manufacturing site for bulk: **KRKA, d.d., Novo mesto** **Šmarješka cesta 6** **Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6** GMP certificate No: **401-12/2018-5**
Name and address of manufacturing site for finished product: **KRKA, d.d., Novo mesto** **Šmarješka cesta 6** **Novo mesto, 8501, Slovenia**	Manufacturing Authorisation No: **800-13/2018-6** GMP certificate No: **401-12/2018-5**
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: **401-12/2018-5**

Quantity of Batch: **3.435 PC**

Delivered quantity: **771 PC**

According to Specification: **DPSPEC001932_3**

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 where reviewed and found to be in compliance with GMP.

Date of release:
14.05.2019

Qualified Person for Batch Release:
Marica Brcar

Quality Management Division
KRKA, d.d. Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Certificate of Analysis

KRKA, d.d., Novo mesto

Date: 16.03.2020

Name of Product: **7A1432 DEHINEL PLUS FLAVOUR tablets for veterinary use**	
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Characteristic	Specification	Results	
Appearance	Yellow colored, round shaped tablets with visible darker spots and bevel-edges with a cross-line 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
Uniformity of dosage units-content uniformity of praziquantel - AV	Max. 15.0	4.6	
Uniformity of dosage units-content uniformity of pyrantel embonate - AV	Max. 15.0	3.7	
Uniformity of dosage units-content uniformity of febantel - AV	Max. 15.0	5.7	
Water	Max. 4.5 %	3.3	
Hardness	90 - 240 Newton	174 -222	
Identification of praziquantel -HPLC	Assay is at the same time identification.	Complies	
Identification of praziquantel - TLC	Complies with the test in the analytical procedure.	Complies	
Identification of pyrantel embonate-HPLC	Assay is at the same time identification.	Complies	
Identification of pyrantel embonate - TLC	Complies with the test in the analytical procedure.	Complies	
Identification of febantel -HPLC	Assay is at the same time identification.	Complies	
Identification of febantel - TLC	Complies with the test in the analytical procedure.	Complies	
Related substances of praziquantel– only one	Max. 0.7 %	<= 0.3	
Related substances of praziquantel- other individually	Max. 0.3 %	<= 0.10	
Related substances of praziquantel - total	Max. 1.2 %	<= 0.10	
Related substances of pyrantel embonate-individually	Max. 0.5 %	0.1	
Related substances of pyrantel embonate - total	Max. 1.2 %	0.1	
Related substances of febantel-individually	Max. 0.3 %	<= 0.10	
Related substances of febantel - total	Max. 0.8 %	<= 0.10	
Content of praziquantel	95.0 - 105.0 % of stated amount	99.7	
Content of pyrantel embonate	95.0 - 105.0 % of stated amount	98.0	
Content of febantel	95.0 - 105.0 % of stated amount	100.6	
Dissolution of praziquantel	Min. 80 % of st.am.in 45 min	97 -100	
Dissolution of pyrantel embonate	Min. 80 % of st.am.in 45 min	97 -100	
Dissolution of febantel	Min. 80 % of st.am.in 45 min	97 -99	
Microbiological quality- TAMC	Max. 1000 CFU/g		*2
Microbiological quality - TYMC	Max. 100 CFU/g		*2
Escherichia coli	Absent in 1 g		*2

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Characteristic	Specification	Results

*1 Testing not performed on every batch (monitoring programe- at least one batch per year).
*2 Testing not performed on every batch (monitoring programe- at least one batch per year).

Date of release:
14.05.2019

Qualified Person for Batch Release:
Marica Brcar

Quality Management Division
KRKA, d.d. Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto, Slovenia