KRKA

KRKA-FARMA d.o.o.

Certificate of Compliance

Date: 16.12.2021.
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Name of Product: **7F4193 DEHINEL PLUS FLAVOUR tablets for dogs**	
Dosage form: **tablets**	Package size: **10 tablets**
Strength/Potency (amount per unit dose): **144 mg / 150 mg / 50 mg**	
Batch No. final product: **H12586**	Customer's batch No.: /
Batch No. bulk: **H12191**	
Date of manufacture: **07.2021**	Expiry date: **07.2024**
Importing country - Marketing Authorisation No.: **RO - 160363**	
Name and address of manufacturing site for bulk : KRKA-FARMA d.o.o. V. Holjevca 20/E, 10450 Jastrebarsko Croatia	Manufacturing Authorisation No.: UP/I-530-01/20-03/05 381-13-08/318-21-10
	Certificate of GMP compliance : UP/I-530-10/20-03/10 381-10-05/241-20-03
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
	Certificate of GMP compliance : 401-12/2018-5
Name and address of quality control: KRKA-FARMA d.o.o. V. Holjevca 20/E, 10450 Jastrebarsko Croatia	Manufacturing Authorisation No.: UP/I-530-01/20-03/05 381-13-08/318-21-10
	Certificate of GMP compliance : UP/I-530-10/20-03/10 381-10-05/241-20-03

Quantity of batch: 2 542 PC
According to specification: SRA1456-5/RMSIE

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.

Date of release: 16.12.2021.

Qualified Person for batch release:
Sanja Matković, MPharm
Quality Management
KRKA-FARMA d.o.o.
V. Holjevca 20/E
10450 Jastrebarsko, Croatia

KRKA

KRKA-FARMA d.o.o.
Site Jastrebarsko
Quality management

Jastrebarsko, 16.12.2021.

CERTIFICATE OF ANALYSIS

Code: **7F4193**

Product: **DEHINEL PLUS FLAVOUR tablets for dogs** Packaging: 10 tablets

Batch No: **H12586** Batch number semiproduct: H12191

Manuf. Date: 07 2021

Exp. Date: 07 2024

TEST	RESULTS	SPECIFICATION
Appearance	Complies	Yellow colored, round, biconvex tablets with visible darker spots, cross-scored on one side. *Note: Nominal mass of tablet is 0.760 g*
Uniformity of dosage units – content uniformity of praziquantel	2.6%	Acceptance value (AV): not more than 15.0%
Uniformity of dosage units – content uniformity of pyrantel embonate	4.2%	Acceptance value (AV): not more than 15.0%
Uniformity of dosage units – content uniformity of febantel	2.4%	Acceptance value (AV): not more than 15.0%
Water (0.50 g of tablet powder, Hydranal Composite 5)	3.0%	Not more than 4.5 %.
[1]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.
Hardness	167-220N	Between 90 N and 240 N.
Identification of praziquantel: **- HPLC** **- TLC**	 Complies Complies	 Assay is at the same time identification. Complies with the test in the analytical procedure.
Identification of pyrantel embonate: **- HPLC** **- TLC**	 Complies Complies	 Assay is at the same time identification. Complies with the test in the analytical procedure.

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CERTIFICATE OF ANALYSIS

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Product: **DEHINEL PLUS FLAVOUR tablets for dogs** Packaging: 10 tablets

Batch No: **H12586** Batch number semiproduct: H12191

Manuf. Date: 07 2021

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TEST	RESULTS	SPECIFICATION
Identification of febantel **- HPLC** **- TLC**	 Complies Complies	 Assay is at the same time identification. Complies with the test in the analytical procedure.
Related substances of praziquantel: - only one - other, individually: - total	 0.11 <= 0.1% 0.11	 Not more than 0.7% Not more than 0.3% Not more than 1.2%
Related substances of pyrantel embonate: - individually: - total	 <= 0.1% <= 0.1%	 Not more than 0.5% Not more than 1.2%
Related substances of febantel: - individually: - total	 <= 0.1% <= 0.1%	 Not more than 0.3% Not more than 0.8%
Content of praziquantel	99.9%	95.0% - 105.0% of the stated amount. (stated amount of praziquantel: 50 mg)
Content of pyrantel embonate	99.2%	95.0% - 105.0% of the stated amount. (stated amount of pyrantel embonate: 144 mg)
Content of febantel	100.1%	95.0% - 105.0% of the stated amount. (stated amount of febantel: 150 mg)
[2]Dissolution of praziquantel Dissolution (75%) Q-Level2-average 12	92%	Not less than 75% (Q) of the stated amount in 45 minutes.
Dissolution (75%) Q-Level2-individual 12	81-102%	Not less than 60% of the stated amount in 45 minutes.

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CERTIFICATE OF ANALYSIS

Code: **7F4193**

Product: **DEHINEL PLUS FLAVOUR tablets for dogs** Packaging: 10 tablets

Batch No: **H12586** Batch number semiproduct: H12191

Manuf. Date: 07 2021

Exp. Date: 07 2024

TEST	RESULTS	SPECIFICATION
[2)]**Dissolution of pyrantel embonate**		
Dissolution (75%) Q-Level2-average 12	90%	Not less than 75% (Q) of the stated amount in 45 minutes.
Dissolution (75%) Q-Level2-individual 12	79-101%	Not less than 60% of the stated amount in 45 minutes.
[2)]**Dissolution of febantel**		
Dissolution (75%) Q-Level2-average 12	90%	Not less than 75% (Q) of the stated amount in 45 minutes.
Dissolution (75%) Q-Level2-individual 12	78-101%	Not less than 60% of the stated amount in 45 minutes.
[3)]**Microbiological quality**: TAMC: TYMC: E.coli:	/	 Max. 1000 CFU/g Max. 100 CFU/g Absent in 1 g

[1)] Not routinely tested (once per year). The test is performed on subdivided parts on halfs of tablets
[2)] The test is performed according to the Ph. Eur. 2.9.3.
[3)] Testing is performed according to the programme:
a) Initially three consecutive batches are tested. If the results are correct continue as follows:
b) At least one batch is tested annually as long as the results comply with the requirements for microbial quality.
c) In case of failure, each batch is tested until 3 consecutive batches complay with the requirements. The testing described under item b) is carried out.

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