KRKA

KRKA-FARMA d.o.o.

Certificate of Compliance

Date: 06.11.2019.
Page: 1/1

Name of Product: **7C9484 DEHINEL 230 MG/20 MG film coated tablets for cats**	
Dosage form: **film coated tablets**	Package size: **2 tablets**
Strength/Potency (amount per unit dose): **230mg/20 mg**	
Batch No. final product: **H10545**	Customer's batch No.: /
Batch No. bulk: **H10390**	
Date of manufacture: **07.2019.**	Expiry date: **07.2021.**
Importing country - Marketing Authorisation No.: **BG - 0022-2712** **RO - 170059** **SI - DC/V/0571/001**	
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-322-05/18-01/446 525-10/0268-18-17
	Certificate of GMP compliance : UP/I-530-10/18-03/11 381-10-05/241-18-03
Name and address of manufacturing site for finished product : KRKA-FARMA d.o.o. V. Holjevca 20/E, 10450 Jastrebarsko Croatia	Manufacturing Authorisation No.: UP/I-322-05/18-01/446 525-10/0268-18-17
	Certificate of GMP compliance : UP/I-530-10/18-03/11 381-10-05/241-18-03
Name and address of quality control: KRKA-FARMA d.o.o. V. Holjevca 20/E, 10450 Jastrebarsko Croatia	Manufacturing Authorisation No.: UP/I-322-05/18-01/446 525-10/0268-18-17
	Certificate of GMP compliance : UP/I-530-10/18-03/11 381-10-05/241-18-03

Quantity of batch: 8 911 PC
According to specification: DPSpec006675/2

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: 06.11.2019.

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

KRKA-FARMA d.o.o. TAŠNER, Šmarješka cesta 42

KRKA

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

Jastrebarsko, 06.11.2019.

CERTIFICATE OF ANALYSIS

Code: 7C9484

Product: **DEHINEL 230 MG/20 MG film coated tablets for cats** Packaging: 2 film coated tablets

Batch No: **H10545** Batch number semiproduct: H10390

Manuf. Date: 07 2019

Exp. Date: 07 2021

TEST	RESULTS	SPECIFICATION
Appearance	Complies	White to almost white, biconvex, oval film coated tablets, scored on one side.
Uniformity of dosage units – content uniformity of praziquantel	1.8	Acceptance value (AV): not more than 15.0 %
Uniformity of dosage units – content uniformity of pyrantel embonate	2.0	Acceptance value (AV): not more than 15.0 %
Uniformity of mass of subdivided tablets	Complies	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.
Identification of praziquantel: **- HPLC** **- [1]TLC**	 Complies Complies	 Assay is at the same time identification. Complies with the test in the analytical procedure.
Identification of pyrantel embonate: **- HPLC** **- [1]TLC**	 Complies Complies	 Assay is at the same time identification. Complies with the test in the analytical procedure.
Related substances of praziquantel: - individual: - total	 <= 0.3% <= 0.3%	 Not more than 0.5% Not more than 2.0%
Related substances of pyrantel embonate: - individual: - total	 <= 0.3% <= 0.3%	 Not more than 0.5% Not more than 1.5%

KRKA-FARMA d.o.o. ZAGREB

Qualified Person for Batch Release:
Maja Staroveški, Mpharm
Quality Management

KRKA

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

Jastrebarsko, 06.11.2019.

CERTIFICATE OF ANALYSIS

Code: 7C9484

Product: **DEHINEL 230 MG/20 MG film coated tablets for cats** Packaging: 2 film coated tablets

Batch No: **H10545** Batch number semiproduct: H10390

Manuf. Date: 07 2019

Exp. Date: 07 2021

TEST	RESULTS	SPECIFICATION
Content of praziquantel	101%	95% - 105% of the stated amount. (stated amount of praziquantel: 20 mg)
Content of pyrantel embonate	101%	95% - 105% of the stated amount. (stated amount of pyrantel embonate: 230 mg)
[2]**Dissolution of praziquantel**	101-103%	Not less than 75% (Q) of the stated amount in 45 minutes.
[2]**Dissolution of pyrantel embonate**	101-103%	Not less than 75% (Q) of the stated amount in 45 minutes.
[3]**Microbiological purity**: TAMC: TYMC: E.coli:	 < 10 < 10 Complies	 Max. 1000 CFU/g Max. 100 CFU/g Absent in 1 g

[1] The test is not performed routinely. The test is performed once per year.
[2] The test is performed according to the Ph. Eur. 2.9.3.
[3] Testing is performed according to the programme.

Qualified Person for Batch Release:
Maja Staroveški, Mpharm
Quality Management

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