



KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany		Certificate of Analysis	Page: 1 of 2 Date: 2016-03-16
Material: 83958847 Your material:		DRONTAL CAT E TABL 1X2 BOX X 1 X 2 TAB. DRONTAL TAB CAT-ELLIPSOID 1X2	
Batch: KP0B2ZF Date of manufacture: 2015-09-15 Expiry date: 2020-09-30	Country: Hungary Delivery number: 107499204 Order number: 6318142		
From material: 04510090 Batch: KP0AZCB Inspection lot: 010002709143	DRONTAL TAB KATZE ELLIPSE - ROTTENDORF - Insp. instruction: T.02.02 - 1 Specification: T.02.28 - 2		

Inspection	Acceptance criterion	UoM	Result
Material (visual)	coated tablet		coated tablet
Colour (visual)	white to yellowish		white
Markings tablet	must comply		complies
Identity Praziquantel	must comply		complies
Identity Pyrantel embonate	must comply		complies
Water	max. 5	%	2
Dissolution Praziquantel	min. 75	%	94
Dissolution Pyrantel embonat	min. 70	%	98
Uniformity of mass min.90%	322-356 MG		complies
Uniformity of mass 100%	305-373 MG		complies
Assay Praziquantel	19.0 - 21.0	mg/Tab	20.5
Assay Pyrantel embonat	219 - 242	mg/Tab	236
Any unspecified degradation product	max. 0.5	%/ACT	< 0.3
Sum of all degradation products	max. 1.0	%/ACT	< 0.3

Diszpó: 5928022108 Vev: ALPHA-VET File név: BA00001858 Egyedi sorozám: BA000002050 3 másolat
 Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 2 / 1 Anyaglap: 500173454
 Az eredetivel megegyez elektronikus másolat a(z):
 - Dr. Gacsályi Panna min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.06.20 CertEx v 3.03a



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Inspection	Acceptance criterion	UoM	Result
Total aerobic microbial count (TAMC)	max. 1000	CFU/g	*)
Total combined yeast/mould count (TYMC)	max. 100	CFU/g	*)
Microb. purity Escherichia coli/1g	absent		*)

*) Test is carried out on spot-check basis. However we confirm compliance with the inspection and requirements also for this batch.

This batch complies with the specification and is manufactured in accordance with EC Guide to GMP for Medicinal Products and the requirement laid down in the product license.

Release Documentation is signed by responsible Person Quality Management.

Batch release electronically signed:

Dr. Carsten Bode (KPCBO)
Qualified Person
2016-03-15 08:06:30 p.m. CET (UTC + 1 hour)
040001561410

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