



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 3 Date: 2015-12-10
Material: 84836559 Your material:		DRONTAL TASTY TAB DOG(DP90) 10KG 17X6 DRONTAL TASTY TAB DOG(DP90) 10KG 17X6		
Batch:	KP0AV77	Country: Hungary		
Date of manufacture:	2015-10-29	Delivery number: 106695875		
Expiry date:	2017-10-31	Order number: 5633804		
From material:	82292861	FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB		Insp. instruction: T.02.02 - 7
Batch:	KP0ATGG	Specification: T.02.28 - 8		
Inspection lot:	040001517952			
Inspection	Acceptance criterion	UoM	Result	
Material (visual)	tablet		tablet	
Colour (visual)	light-brown to brown		brown	
Markings tablet	score on both sides		score on both sides	
Odour	characteristic, liver aroma		characteristic, liver aroma	
Hardness	80 - 170	N	148	
Tablet weight	978 - 1196	mg	1080	
Identity Praziquantel	must comply		complies	
Identity Pyrantel Embonate	must comply		complies	
Identity Febantel	must comply		complies	
Identity Praziquantel (UV)	must comply		complies	
Identity Pyrantel embonate (UV)	must comply		complies	
Identity Febantel (UV)	must comply		complies	
Water	max. 7.0	%	4.9	
Dissolution Praziquantel after 15 min	min. 80	%	100	

Diszpó: 5928019800 Vev: ALPHA-VET File név: BA00001795 Egyedi sorszám: BA000001901 10 másolat
 Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 3 / 1 Anyaglap: 500165725
 Az eredetivel megegyez elektronikus másolat a(z):
 Dr. Gacsályi Panna min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.01.25 CertEx v 3.03a



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Inspection	Acceptance criterion	UoM	Result
Dissolution Pyrantel embonate after 15min	min. 80	%	99
Dissolution Febantel after 15 min	min. 80	%	104
Uniformity of dosage units (mass)	must comply		complies
Any unspecified degradation product	max. 0.50	%	< 0.20
Sum of all degradation products	max. 1.0	%	0.3
Assay Praziquantel	47.5 - 52.5	mg/Tab	50.1
Assay Pyrantel embonat	136.0 - 152.0	mg/Tab	144.9
Assay Febantel	142.0 - 158.0	mg/Tab	151.7
Total aerobic microbial count (TAMC)	max. 1000	CFU/g	*)
Total combined yeast/mould count (TYMC)	max. 100	CFU/g	*)
Escherichia coli	Absence in 1 g		*)

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 Dr. Gacsályi Panna min.biol.gyógyszerész által küldve. Nyomtatás dátuma: 2016.01.25 CertEx v 3.03a



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*) 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
Date/time: 2015-12-09 06:44:30 p.m. CET (UTC + 1 hour)
Inspection lot: 040001527797

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