



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 3 Date: 2013-07-17
Material: 84529177 Your Material:		DRONTAL PLUS 10 KG FBG 18X6 TABL BOX 18 X 6 TABL DRONTAL PLUS 10 KG FBG 18X6 TABL		
Batch:	KP08RDD	Country: Hungary		
Date of manufacture:	2013-04-17	Delivery number: 100871538		
Expiry date:	2018-04-30	Order number: 1493140		
From Material:	06748635	FEB+PRAZ+PYR TAB 150+50+144MG FLAV BONE		
Batch:	KP08N53	Insp. instruction:	T.02.02 - 1	
Inspection lot:	040001119534	Specification:	T.02.01 - 1	
Inspection	Acceptance criterion	UoM.	Result	
Material (visual)	tablet		tablet	
Colour (visual)	light-brown to brown		light brown	
Shape (visual)	bone shaped		bone shaped	
Markings tablet	score on both sides		score on both sides	
Odour	characteristic		complies	
Identity Praziquantel	must comply		complies	
Identity Pyrantel Embonate	must comply		complies	
Identity Febantel	must comply		complies	
Water	max. 5	%	2	
Dissolution praziquantel after 30 min.	min. 75	%	97	
Dissolution pyrantelembonate aft.30min	min. 70	%	101	
Dissolution febantel after 30 min	min. 70	%	100	
Uniformity of mass min. 90%	min.18 s.u. in 737-815 mg		complies	
Uniformity of mass 100%	20 s.u. in 698-854 mg		complies	



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Inspection	Acceptance criterion	UoM.	Result
Any unspecified degradation product	max. 0.5	%	< 0.3
Sum of all degradation products	max. 1.0	%	< 0.3
Assay Praziquantel	47.5 - 52.5	mg/Tab	50.1
Assay Pyrantelmonat	136 - 152	mg/Tab	146
Assay Febantel	142 - 158	mg/Tab	153
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		*)

*) 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 - Dr. Amann - QP

Bayer HealthCare

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