



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis		Page: 1 of 3 Date: 2013-11-27
Material: 81622256 Your Material:	DRONTAL PLUS 10 KG FBG 18X6 TABL BOX 18 X 6 TABL DRONTAL PLUS 10 KG FBG 18X6 TABL		
Batch: KP093ZT Date of manufacture: 2013-08-19 Expiry date: 2018-08-31	Country: Hungary Delivery number: 101441499 Order number: 1965174		
From Material: 06748635 Batch: KP08XNB Inspection lot: 040001175892	FEB+PRAZ+PYR TAB 150+50+144MG FLAV BONE		Insp. instruction: T.02.02 - 1 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	%	3
Dissolution praziquantel after 30 min.	min. 75	%	98
Dissolution pyrantel embonate aft.30min	min. 70	%	98
Dissolution febantel after 30 min	min. 70	%	98
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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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	49.4
Assay Pyrantelmonat	136 - 152	mg/Tab	142
Assay Febantel	142 - 158	mg/Tab	149
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



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