



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis	Page: 1 of 2 Date: 2013-11-12
Material: 83431858 Your Material:	DRONTAL PLUS XL TAB DOG FLAV G 1X2 BOX 2 ST DRONTAL PLUS XL TAB DOG FLAV G 1X2	
Batch: KP092G0 Date of manufacture: 2013-08-19 Expiry date: 2016-08-31	Country: Hungary Delivery number: 101371642 Order number: 1965172	
From Material: 06531520 Batch: KP08X92 Inspection lot: 040001174739	FEB+PRAZ+PYR TABL 525+175+504 MG FLAV	Insp. instruction: T.02.02 - 3 Specification: T.02.01 - 4

Inspection	Acceptance criterion	UoM.	Result
Material (visual)	tablet		tablet
Colour (visual)	light-brown to brown		light brown
Markings tablet	must comply		complies
Odour	characteristic		complies
Identity Praziquantel	must comply		complies
Identity Pyranate Embonate	must comply		complies
Identity Febantel	must comply		complies
Water	max. 5	%	3
Dissolution Praziquantel	min. 75	%	93
Dissolution Pyranatelembonat	min. 70	%	83
Dissolution Febantel	min. 70	%	75
Uniformity of mass min. 90%	min.18 s.u. in 2582-2854 mg		complies
Uniformity of mass 100%	20 s.u. in 2446-2990 mg		complies
Any unspecified degradation product	max. 1.0	%	< 0.3
Sum of all degradation products	max. 2.0	%	< 0.3



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Inspection	Acceptance criterion	UoM.	Result
Assay Praziquantel	166 - 184	mg/Tab	180
Assay Pyrantelmonat	479 - 529	mg/Tab	518
Assay Febantel	499 - 551	mg/Tab	539
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 - Dr. Amann - QP

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