



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		<b>Certificate of Analysis</b>		Page: 1 of 2 Date: 2014-05-06
Material: 83044730 Your Material:		DRONTAL TABLET CAT ELLIPSOID 1X2 BOX X 1 X 2 TAB. DRONTAL CAT 1X2 TAB. ELLIPSOID		
Batch:	KP09GDA	Country: Hungary		
Date of manufacture:	2013-09-18	Delivery number: 102324463		
Expiry date:	2018-09-30	Order number: 2467082		
From Material:	04510090	DRONTAL TAB KATZE ELLIPSE - ROTTENDORF -		
Batch:	KP09EKT	Insp. instruction:	T.02.02 - 1	
Inspection lot:	010002348661	Specification:	T.02.01 - 1	
Inspection	Acceptance criterion	UoM.	Result	
Material (visual)	coated tablet		coated tablet	
Colour (visual)	white to yellowish		yellowish white	
Markings tablet	must comply		complies	
Identity Praziquantel	must comply		complies	
Identity Pyranate Embonate	must comply		complies	
Water	max. 5	%	2	
Dissolution Praziquantel	min. 75	%	93	
Dissolution Pyranatelembonat	min. 70	%	94	
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	20.6	
Assay Pyranatelembonat	219 - 242	mg/Tab	233	
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	
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

This Certificate of Analysis was automatically printed.