

DRONTAL PLUS 150/144/50MG DOG 6X
 Gysz: KV02S8C Lej: 2023-09-30
 Kisz: 6X Me: Doboz
 SZÉKELY KFT részére

Szállító:
 Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6476
 e-mail: qa@mpx.hu



Inspection	Acceptance criterion	UoM	Result
Material (visual)	tablet		tablet
Colour (visual)	light-brown to brown		light brown
Markings tablet	score on both sides		score on both sides
Odour	characteristic, liver aroma		characteristic, liver aroma
Hardness	80 - 170	N	164
Tablet weight	978 - 1196	mg	1089
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	%	5.1
Dissolution Prazi. after 15 min.(Q=80%)	min. 85	%	90

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KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany		Certificate of Analysis		Page: 2 of 3 Date: 2021-03-10
Material: 84744948 Your material:		DRONTAL TASTY TAB DOG (DP90)10KG 1X6 VTQ DRONTAL TASTY TAB DOG (DP90) 10KG 1X6 FB 1X6 TAB - 460966		
Batch: KV02S8C Date of manufacture: 2020-09-28 Expiry date: 2023-09-30	Country: France Delivery number: 80494552 Order number: 700163491			
From material: 82292861 Batch: KV02A8T Inspection lot: 890000003980	FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB Insp. instruction: T.02.02 - 9 Specification: T.02.28 - 11			
Inspection	Acceptance criterion	UoM	Result	
Dissolution Pyran.after 15 min.(Q=80%)	min. 85	%	90	
Dissolution Feban.after 15 min.(Q=80%)	min. 85	%	92	
Uniformity of dosage units (mass)	must comply		complies	
Any unspecified degradation product	max. 0.50	%/ACT	0.23	
Sum of all degradation products	max. 1.0	%/ACT	0.3	
Assay Praziquantel	47.5 - 52.5	mg/Tab	49.8	
Assay Pyrantelmonat	136.0 - 152.0	mg/Tab	140.5	
Assay Febantel	142.0 - 158.0	mg/Tab	146.8	
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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*) Test is carried out on spot-check basis. However we confirm compliance with the inspection and requirements also for this batch.

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Release Documentation is signed by responsible Person Quality Management.

Batch release electronically signed: Dr. Andreas Engwicht-Lassmann (TGENW)
Qualified Person
Date/time: 2021-03-05 04:01:26 p.m. CET (UTC + 1 hour)
Inspection lot: 040000012249

This Certificate of Analysis was automatically printed.