

DRONTAL PLUS 150/144/50MG DOG 102X
 Gysz: KV02L6V Lej: 2023-07-31
 Kisz: 102X Me: Doboz
 SZÉKELY KFT részére

Szállító:
 Medimpex Gy. Zrt.
 1158 Budapest
 Rákospalotaihatárút2
 Tel: +36-1-414-6476
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KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany		Certificate of Analysis		Page: 1 of 3 Date: 2021-02-24
Material: 84836559 Your material:		DRONTAL TASTY TAB DOG(DP90)10KG 17X6 VTQ DRONTAL TASTY TAB DOG(DP90) 10KG 17X6 - 460944		
Batch: KV02L6V Date of manufacture: 2020-07-06 Expiry date: 2023-07-31	Country: France Delivery number: 80451208 Order number: 700103495			
From material: 82292861 Batch: KP0F9D7 Inspection lot: 890000000500	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	
Material (visual)	tablet		tablet	
Colour (visual)	light-brown to brown		brown	
Markings tablet	score on both sides		score on both sides	
Odour	characteristic, liver aroma		characteristic, liver aroma	
Hardness	80 - 170	N	154	
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	%	5.8	
Dissolution Prazi.after 15 min.(Q=80%)	min. 85	%	97	

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Inspection	Acceptance criterion	UoM	Result	
Dissolution Pyran.after 15 min.(Q=80%)	min. 85	%	97	
Dissolution Feban.after 15 min.(Q=80%)	min. 85	%	95	
Uniformity of dosage units (mass)	must comply		complies	
Any unspecified degradation product	max. 0.50	%/ACT	0.16	
Sum of all degradation products	max. 1.0	%/ACT	0.4	
Assay Praziquantel	47.5 - 52.5	mg/Tab	51.4	
Assay Pyrantelmonat	136.0 - 152.0	mg/Tab	151.6	
Assay Febantel	142.0 - 158.0	mg/Tab	153.0	
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:

2021-02-17 08:08:02 a.m. CET (UTC + 1 hour)

Inspection lot:

040000009792

This Certificate of Analysis was automatically printed.