DRONTAL PLUS 150/144/50MG DOG 6X
Gysz: KV02PLH Lej: 2023-09-30
Kisz: 6X Me: Doboz
SZÉKELY KFT részére

Szállító:
Medimpex Gy. Zrt.
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e-mail: qa@mpx.hu

KVP
Pharma + Veterinär Produkte

KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany	**Certificate of Analysis**	Page: 1 of 3 Date: 2021-02-24

Material: 84744948 Your material:	DRONTAL TASTY TAB DOG (DP90)10KG 1X6 VTQ DRONTAL TASTY TAB DOG (DP90) 10KG 1X6 FB 1X6 TAB - 460966

Batch:	KV02PLH	Country: France	
Date of manufacture:	2020-09-28	Delivery number: 80451203	
Expiry date:	2023-09-30	Order number: 700163429	
From material:	82292861	FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB	
Batch:	KV02A8T	Insp. instruction:	T.02.02 - 9
Inspection lot:	890000003709	Specification:	T.02.28 - 11

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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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 Pyrantelembonat	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:	2021-02-16 10:45:42 a.m. CET (UTC + 1 hour)
Inspection lot:	040000011484

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