Szállító:
Medimpex Gy. Zrt.
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KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany	Certificate of Analysis	Page: 1 of 4 Date: 2019-12-06
Material: 84744948 Your material:	DRONTAL TASTY TAB DOG (DP90) 10KG 1X6 DRONTAL TASTY TAB DOG (DP90) 10KG 1X6 FB 1X6 TAB	

Batch:	KP0ELPG	Country: Hungary	
Date of manufacture:	2019-10-11	Delivery number: 120234876	
Expiry date:	2022-10-31	Order number: 706916409	
From material:	82292861	FEB/PRAZ/PYR 150/50/144MG TREAT 10KG TAB	
Batch:	KP0EGS6	Insp. instruction:	T.02.02 - 9
Inspection lot:	040002117891	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	1086
Identity Praziquantel	must comply		complies
Identity Pyrantel embonate	must comply		complies
Identity Febantel	must comply		complies
Identity Praziquantel (UV)	must comply		complies

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Inspection	Acceptance criterion	UoM	Result
Identity Pyrantel embonate (UV)	must comply		complies
Identity Febantel (UV)	must comply		complies
Water	max. 7.0	%	5.7
Dissolution Prazi.after 15 min.(Q=80%)	min. 85	%	100
Dissolution Pyran.after 15 min.(Q=80%)	min. 85	%	98
Dissolution Feban.after 15 min.(Q=80%)	min. 85	%	101
Uniformity of dosage units (mass)	must comply		complies
Any unspecified degradation product	max. 0.50	%/ACT	0.29
Sum of all degradation products	max. 1.0	%/ACT	.0.5
Assay Praziquantel	47.5 - 52.5	mg/Tab	49.7

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Inspection	Acceptance criterion	UoM	Result
Assay Pyrantelembonat	136.0 - 152.0	mg/Tab	144.0
Assay Febantel	142.0 - 158.0	mg/Tab	148.2
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		*)

*) 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 and/or marketing authorisation.

Release Documentation is signed by responsible Person Quality Management.

Batch release electronically signed: Dr. Robert Reh (KPRRE)
Qualified Person
Date/time: 2019-12-05 05:00:05 p.m. CET (UTC + 1 hour)
Inspection lot: 040002133655

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