

DRONTAL CAT TABLETTA FÉREGHAJTÓ MACSKA

Gysz: KP0F0AS

Lej: 2024-09-30

Kisz: 2X

Me: Doboz

SZÉKELY KFT részére

Szállító:

Medimpex Gy. Zrt.

1158 Budapest

Rákospalotaihatárút2

Tel: +36-1-414-6477

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KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2020-04-30
Material: 83958847 Your material:		DRONTAL CAT E TABL 1X2 BOX X 1 X 2 TAB. DRONTAL TAB CAT ELLIPSOID 1X2		
Batch: KP0F0AS Date of manufacture: 2019-09-27 Expiry date: 2024-09-30	Country: Hungary Delivery number: 121430950 Order number: 707851653			
From material: 04510090 Batch: KP0EUJV Inspection lot: 010006144596	DRONTAL TAB KATZE ELLIPSE - ROTTENDORF - Insp. instruction: T.02.02 - 1 Specification: T.02.28 - 2			
Inspection	Acceptance criterion	UoM	Result	
Material (visual)	coated tablet		coated tablet	
Colour (visual)	white to yellowish		white	
Markings tablet	must comply		complies	
Identity Praziquantel	must comply		complies	
Identity Pyrantel embonate	must comply		complies	
Water	max. 5	%	2	
Dissolution Praziquantel	min. 75	%	90	
Dissolution Pyranterlemonat	min. 70	%	95	
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	20.4	
Assay Pyranterlemonat	219 - 242	mg/Tab	235	
Any unspecified degradation product	max. 1.0	%/ACT	< 0.3	
Sum of all degradation products	max. 2.0	%/ACT	< 0.3	
Total aerobic microbial count (TAMC)	max. 1000	CFU/g	*)	

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Inspection	Acceptance criterion	UoM	Result	
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 and/or marketing authorisation.

Release Documentation is signed by responsible Person Quality Management.

Batch release electronically signed:

Kenyatta Pinder (GLEBN)
Qualified Person

Date/time:

2020-04-16 04:50:08 p.m. CET (UTC + 1 hour)

Inspection lot:

040002231772

This Certificate of Analysis was automatically printed.