KVP
Pharma + Veterinär Produkte

KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany	**Certificate of Analysis**	Page: 1 of 3 Date: 2023-01-16

Material: 81511713 Your material:	PROCOX ORAL SUSPENSION 7.5 ML PROCOX ORAL SUSPENSION 7.5 ML
Countries to be supplied:	Moldova, Ukraine, Azerbaijan

Sales Batch:	KV04F6S		Country: Ukraine
Date of manufacture:	2022-02-10		Delivery number: 82014236
Expiry date:	2024-02-29		Order number: 701829842
From material:	86037122	EMO+TOLT 0.1+2.0% OILY SUSP 7.5ML CORK	
Batch:	KV042VC		Insp. instruction: T.02.02 - 5
Inspection lot:	040000032824		Specification: T.02.28 - 5

Inspection	Acceptance criterion	UoM	Result
Material (visual)	suspension		suspension
Colour (visual)	white to yellow-white		yellow-white
Identity Emodepside (HPLC)	must comply		complies
Identity Toltrazuril (HPLC)	must comply		complies
Identity Emodepside (fluorescence)	must comply		complies
Identity Toltrazuril (fluorescence)	must comply		complies
Identity Sorbic acid	must comply		complies
Identity Butylhydroxytoluene (HPLC)	must comply		complies
Suspendability	must comply		complies
Extractable volume	must comply		complies
Viscosity	75 - 225	mPa.s	136
Particle size X10, initial	max. 10	µm	2
Particle size X90, initial	max. 40	µm	17
Emodepside	0.095 - 0.105	g/100g	0.099
Toltrazuril	1.9 - 2.1	g/100g	2.0
Butylhydroxytoluene	0.09 - 0.11	g/100g	0.11

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Sorbic acid	0.072 - 0.088	g/100g	0.079
N-oxide	max. 1.0	%	< 0.4
Any unspecified degrad.product, largest	max. 1.0	%	< 0.4
Total unspec.degradation products	max. 1.5	%	< 0.4
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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Inspection	Acceptance criterion	UoM	Result

*) Test is carried out on spot-check basis. However we confirm compliance with the inspection and requirements also for this batch.
Certification statement:

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: 2022-08-31 05:38:45 p.m. CET (UTC + 1 hour)
Inspection lot: 040000038215

This Certificate of Analysis was automatically printed.