



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	<b>Certificate of Analysis</b>	Page: 1 of 2 Date: 2014-02-13
Material: 81616957 Your Material:	ADVOCATE SO DOGS 3 X 4,0 ML BOX X 3 PIP X 4,0 ML ADVOCATE SO DOGS 3 X 4,0 ML	
Batch: KP09AVX Date of manufacture: 2013-12-16 Expiry date: 2016-12-31	Country: Hungary Delivery number: 101820412 Order number: 2312780	
From Material: 81245401 IMI10%/MOXI 2,5 % H 4,0 ML 81094160 Batch: KP097UR Inspection lot: 040001213333	Insp. instruction: T.02.02 - 6 Specification: T.02.01 - 4	

Inspection	Acceptance criterion	UoM.	Result
Material (visual)	Solution		solution
Clarity (visual)	clear		clear
Colour (Ph.Eur.)	yellow to brownish-yellow		yellow
Identity (HPLC)	must comply		complies
Identity (TLC)	must comply		complies
Assay Imidacloprid	9.5 - 10.5	g/hml	10.1
Any unspecified degrad. prod. Imidacloprid	max. 1.0	%	0.3
Sum of all degrad. products imidacloprid	max. 1.0	%	0.3
Assay Moxidectin	2.25 - 2.62	g/hml	2.53
23-Keto-F-Alpha compound	max. 2.0	%	< 0.1
Any unspecified degrad. prod. Moxidectin	max. 1.0	%	0.5
Sum of all degrad. products moxidectin	max. 4.0	%	0.5
Relative density (USP)	1.093 - 1.103		1.099
Butylhydroxytoluene	0.050 - 0.125	g/hml	0.111
Water	max. 6.0	%	< 0.3



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Inspection lot:	040001213333	Specification:	T.02.01 - 4	
Inspection	Acceptance criterion	UoM.	Result	
Uniformity of content	must comply		complies	
Total aerobic microbial count (TAMC)	max. 100	CFU/g	*)	
Total combined yeast/mould count (TYMC)	max. 10	CFU/g	*)	
Microb.purity Staphylococcus aureus/1g	absent		*)	
Microbial purity Pseudomonas aerug./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.

Release Documentation is signed by Responsible Person Quality Management - Dr. Amann - QP

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