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Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	**Certificate of Analysis**	Page: 1 of 2 Date: 2014-02-07
Material: 81616906 Your Material:	ADVOCATE SO DOGS 3 X 1,0 ML BOX X 3 PIP X 1,0 ML ADVOCATE SO DOGS 3 X 1,0 ML	
Batch: KP099EX Date of manufacture: 2013-11-12 Expiry date: 2016-11-30		Country: Hungary Delivery number: 101781107 Order number: 2462502
From Material: 81245266 IMI10%/MOXI 2,5 % H 1,0 ML 81094136 Batch: KP09586 Inspection lot: 040001202692		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	2.47
23-Keto-F-Alpha compound	max. 2.0	%	< 0.1
Any unspecified degrad. prod.Moxidectin	max. 1.0	%	0.6
Sum of all degrad. products moxidectin	max. 4.0	%	1.2
Relative density (USP)	1.093 - 1.103		1.099
Butylhydroxytoluene	0.050 - 0.125	g/hml	0.106
Water	max. 6.0	%	0.3

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Batch: Date of manufacture: Expiry date:	KP099EX 2013-11-12 2016-11-30	Country: Hungary Delivery number: 101781107 Order number: 2462502

From Material: Batch: Inspection lot:	81245266 IMI10%/MOXI 2,5 % H 1,0 ML 81094136 KP09586 040001202692	Insp. instruction: Specification:	T.02.02 - 6 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

This Certificate of Analysis was automatically printed.