Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	**Certificate of Analysis**	Page: 1 of 2 Date: 2014-01-21

Material: 81852588 Your Material:	BAYCOX 5% 1000 ML PLASTIC BOTTLE X 1000 ML BAYCOX 5% 1000 ML

Batch:	KP09819	Country: Hungary	
Date of manufacture:	2013-10-09	Delivery number: 101660354	
Expiry date:	2018-10-31	Order number: 2107865	
From Material:	05352290 BAYCOX SUSPENSION 5% G/V N	Insp. instruction:	T.02.02 - 7
Batch:	KP09486	Specification:	T.02.01 - 11
Inspection lot:	040001199079		

Inspection	Acceptance criterion	UoM.	Result
Material (visual)	suspension		suspension
Colour (visual)	white to yellowish		white
Identity	must comply		complies
Relative density	1.020 - 1.040		1.033
pH-value	4.0 - 5.0		4.3
Particle size D90	<10 µm		<10
Particle size D99	<30 µm		<30
Sodium benzoate	0.18 - 0.23	g/hml	0.21
Sodium propionate	0.18 - 0.23	g/hml	0.21
Any unspecified impurity	max. 0.5	%	< 0.3
Sum of all impurities	max. 1.0	%	< 0.3
Viscosity	20 - 100	mPa.s	43
Assay	4.75 - 5.25	g/hml	4.94
Total aerobic microbial count (TAMC)	max. 100	CFU/g	*)
Total combined yeast/mould count (TYMC)	max. 10	CFU/g	*)
Escherichia coli	Absence in 1 g		*)

Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	**Certificate of Analysis**	Page: 2 of 2 Date: 2014-01-21
Material: 81852588 Your Material:	BAYCOX 5% 1000 ML PLASTIC BOTTLE X 1000 ML BAYCOX 5% 1000 ML	
Batch: KP09819 Date of manufacture: 2013-10-09 Expiry date: 2018-10-31		Country: Hungary Delivery number: 101660354 Order number: 2107865
From Material: 05352290 BAYCOX SUSPENSION 5% G/V N Batch: KP09486 Inspection lot: 040001199079		Insp. instruction: T.02.02 - 7 Specification: T.02.01 - 11

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.

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.