Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis	Page: 1 of 2 Date: 2015-11-10
Material: 84675997 Your material:	BAYTRIL 10% INJ. 100 ML GLASS BOTTLE X 100 ML BAYTRIL 10% INJ. 100 ML	

Batch:	KP0ASPC	Country: Hungary
Date of manufacture:	2015-07-12	Delivery number: 106440313
Expiry date:	2019-07-31	Order number: 5599483

From material:	06713882	BAYTRIL INJ SOL 10% M/V 100ML	
Batch:	AH014G3	Insp. instruction:	T.02.02 - 6
Inspection lot:	010002648442	Specification:	T.02.28 - 8

Inspection	Acceptance criterion	UoM	Result
Formulation	Solution		solution
Clarity	clear		clear
Colour (visual)	max.Y4 or BY4 or GY4		GY6
Identity (Enrofloxacin)	must comply with the reference substance		complies
Identity (n-Butanol)	must comply with the reference substance		complies
Extractable volume	min. 100.0	ml	102.0
Purity (visual)	free from visible impurities		free from visible impurities
Relative density	1.032 - 1.037		1.034
pH-value	10.8 - 11.8		11.5
n-Butanol	2.70 - 3.30	g/hml	2.84
Assay	9.5 - 10.5	g/hml	10.0
Any unspecified degradation product	max. 0.3	%	0.1
Total unspec.degradation products	max. 1.0	%	0.1

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Inspection	Acceptance criterion	UoM	Result
Sum of all impurities	max. 1.5	%	0.2
Ciprofloxacin	max. 1.0	%	0.1
Sterility	sterile		sterile
Endotoxins	<25 E.U./ml		<7.68

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 Mrs. Cordula Weber, Dr. Bode or Dr. Amann

Batch release electronically signed:	Dr. Carsten Bode (KPCBO) Qualified Person
Date/time:	2015-11-09 07:04:35 p.m. CET (UTC + 1 hour)
Inspection lot:	040001514752

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