Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis	Page: 1 of 2 Date: 2015-10-08
Material: 81600309 Your material:	BAYTRIL MAX 100 ML GLASSBOTTLE X 100 ML BAYTRIL MAX 100 ML	
Batch: KP0ALSE Date of manufacture: 2015-06-07 Expiry date: 2018-06-30		Country: Hungary Delivery number: 106138865 Order number: 5244648
From material: 80931833 Batch: AH0134P Inspection lot: 010002622293	BAYTRIL INJ. LOES 10 % MAX 100 ML	Insp. instruction: T.02.02 - 10 Specification: T.02.28 - 10

Inspection	Acceptance criterion	UoM	Result
Material (visual)	Solution		solution
Colour (visual)	max.Y2		Y5
Clarity (visual)	clear		clear
Appear.primary packaging material	must comply		complies
Identity (UV)	must comply with reference spectrum		complies
Identity (HPLC)	MUST COMPLY TO REFERENCE STANDARD		complies
Extractable volume	101 - 105	ml	102
Relative density	1.07 - 1.09		1.08
pH-value	9.5 - 10.5		10.0
Benzyl alcohol	1.9 - 2.1	g/hml	2.0
Butanol	2.8 - 3.2	g/hml	2.8
Assay	9.5 - 10.5	g/hml	9.9
Ciprofloxacin	max. 1.0	%	0.3

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Batch:	KP0ALSF	Country: Hungary
Date of manufacture:	2015-06-07	Delivery number: 106138865
Expiry date:	2018-06-30	Order number: 5244648

From material:	80931833	BAYTRIL INJ. LOES 10 % MAX 100 ML	Insp. instruction: T.02.02 - 10
Batch:	AH0134P		Specification: T.02.28 - 10
Inspection lot:	010002622293		

Inspection	Acceptance criterion	UoM	Result
Any unspecified degradation product	max. 0.3	%	< 0.3
Sum of all degradation products	max. 1.5	%	0.3
Sterility	sterile		sterile
Endotoxins	<40 E.U./ml		<40
Purity (visual)	free from visible impurities		free from visible impurities

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:	2015-10-07 11:57:22 a.m. CET (UTC + 1 hour)
Inspection lot:	040001495643

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