



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 Date of manufacture: 2015-07-12 Expiry date: 2019-07-31	Country: Hungary Delivery number: 106440313 Order number: 5699483		
From material: 06713882 Batch: AH014G3 Inspection lot: 010002648442	BAYTRIL INJ SOL 10% M/V 100ML		Insp. instruction: T.02.02 - 6 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

Diszpó: 5928019480    Vev: ALPHA-VET    File név: BA00001771    Egyedi sorszám: BA000001879 2 másolat  
 Szállító: Bayer Állat gyógyászati Üzletág    Oldal/Lap 2 / 1    Anyaglap: 500160895  
 Az eredetivel megegyez elektronikus másolat a(z):  
 Dr. Gacsályi Panna min.bízt.gyógyszerész által küldve.    Nyomtatás dátuma: 2016.01.05    **CertEx v 3.03a**



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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		Insp. instruction: T.02.02 - 6
Batch:	AHG14G3	Specification: T.02.28 - 8		
Inspection lot:	010002646442			
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

This Certificate of Analysis was automatically printed.

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