



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2015-10-08
Material: 84867714 Your material:		BAYTRIL 5% INJ. 100 ML GLASS BOTTLE X 100 ML BAYTRIL 5% INJ. 100 ML		
Batch:	KP0ALS9	Country: Hungary		
Date of manufacture:	2015-05-14	Delivery number: 106138835		
Expiry date:	2019-05-31	Order number: 5244630		
From material:	06713866	BAYTRIL INJ SOL 5% M/V 100ML		Insp. instruction: T.02.02 - 6
Batch:	AH011W7	Specification: T.02.28 - 8		
Inspection lot:	010002603354			
Inspection	Acceptance criterion	UoM	Result	
Formulation	Solution		solution	
Clarity	clear		clear	
Colour (visual)	max. Y4 or BY4 or GY4		Y7	
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	101.6	
Purity (visual)	free from visible impurities		free from visible impurities	
Relative density	1.011 - 1.017		1.015	
pH-value	10.8 - 11.8		11.6	
n-Butanol	2.70 - 3.30	g/ml	2.93	
Assay	4.75 - 6.25	g/ml	4.88	
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: BA00001748 Egyedi sorszám: BA000001879 2 másolat
 Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 2 / 1 Anyaglap: 500158062
 Az eredetivel megegyez elektronikus másolat a(z):
 Dr. Gacsályi Panna min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.01.05 **CertEx v 3.03a**



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Inspection lot:	010002603354			
Inspection	Acceptance criterion	UoM	Result	
Sum of all impurities	max. 1.5	%	0.2	
Ciprofloxacin	max. 1.0	%	0.2	
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: 2015-10-08 11:46:23 a.m. GET (UTC + 1 hour)
Inspection lot: 040001495519

This Certificate of Analysis was automatically printed.

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