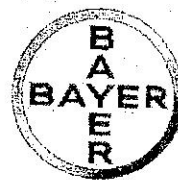




KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany	Certificate of Analysis		Page: 1 of 2 Date: 2016-06-08
Material: 84675997 Your material:	BAYTRIL 10% INJ. 100 ML GLASS BOTTLE X 100 ML BAYTRIL 10% INJ. 100 ML		
Batch: KPO88HL Date of manufacture: 2016-02-10 Expiry date: 2020-02-29	Country: Hungary Delivery number: 108298279 Order number: 6745437		
From material: 06713882 Batch: AH01G89 Inspection lot: 010002767732	BAYTRIL INJ SOL 10% M/V 100ML		insp. instruction: T.02.02 - 6 Specification: T.02.28 - 6

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	102.1
Purity (visual)	free from visible impurities		free from visible impurities
Relative density	1.032 - 1.037		1.033
pH-value	10.8 - 11.8		11.5
n-Butanol	2.70 - 3.30	g/ml	2.93
Assay	9.5 - 10.5	g/ml	10.0
Any unspecified degradation product	max. 0.3	%	< 0.1
Total unsp. degradation products	max. 1.0	%	0.1

Diszpó: 5928023262 Vev: ALPHA-VET File név: BA00001935 Egyedi sorozám: BA000002112 2 másolat
 Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 2 / 1 Anyaglap: 500183848
 Az eredetivel megegyez elektronikus másolat a(z):
 Gyriiné dr. min. bizt. gyógyszerész által küldve. Nyomtatás dátuma: 2016.09.01 CertEx v 3.03a



KVP Pharma+Veterinär Produkte GmbH Projensdorfer Straße 324 24106 Kiel, Germany	Certificate of Analysis	Page: 2 of 2 Date: 2016-06-08	
Material: 84675997 Your material:	BAYTRIL 10% INJ. 100 ML GLASS BOTTLE X 100 ML BAYTRIL 10% INJ. 100 ML		
Batch: KPO88HL Date of manufacture: 2016-02-10 Expiry date: 2020-02-29	Country: Hungary Delivery number: 108298279 Order number: 6745437		
From material: 06713882 Batch: AH01G89 Inspection lot: 010002767732	BAYTRIL INJ SOL 10% MV 100ML Insp. instruction: T.02.02 - 3 Specification: T.02.28 - 6		
Inspection	Acceptance criterion	UoM	Result
Sum of all impurities	max. 1.5	%	0.3
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.

Batch release electronically signed:

Dr. Carsten Bode (KPCBO)
Qualified Person
2016-06-07 06:09:13 p.m. CET (UTC + 1 hour)
040001597754

Date/time:
Inspection lot:

This Certificate of Analysis was automatically printed.

Diszpó: 5928023262 Vev: ALPHA-VET File név: BA00001935 Egyedi sorszám: BA000002112 2. másolat
Szállító: Bayer Állat gyógyászati Üzletág Oldal/Lap 2 / 2 Anyaglap: 500183848
Az eredetivel megegyez elektronikus másolat a(z):
Gyriné dr. min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.09.01 CertEx v 3.03a