



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis		Page: 1 of 3 Date: 2015-04-08
Material: 84509604 Your material:	BAYTRIL 0.5% ORAL SOLUTION 100 ML BOTTLE X 100 ML BAYTRIL 0.5% ORAL SOLUTION 100 ML		
Batch: KP0A8ZD Date of manufacture: 2015-01-08 Expiry date: 2018-01-31	Country: Hungary Delivery number: 104580198 Order number: 4193303		
From material: 00865966 Batch: KP0A30E Inspection lot: 040001385764	BAYTRIL LOESG 0,5% G/V ORAL		Insp. instruction: T.02.02 - 7 Specification: T.02.28 - 10
Inspection	Acceptance criterion	UoM	Result
Material (visual)	Solution		solution
Colour (visual)	yellow-tinged		yellow-tinged
Clarity (visual)	light turbid		complies
Surface property	viscous		viscous
Identity	must comply		complies
Relative density	1.007 - 1.017		1.012
pH-value	10.5 - 11.5		11.0
Benzyl alcohol	1.26 - 1.54	g/hml	1.27
Assay	0.48 - 0.53	g/hml	0.49
Ciprofloxacin	max. 0.5	%	0.2
Any unspecified impurity	max. 0.3	%	0.1
Sum of unspecified impurities	max. 1.0	%	0.1
Total aerobic microbial count (TAMC)	max. 100	CFU/g	*)
Total combined yeast/mould count (TYMC)	max. 10	CFU/g	*)

Diszpó: 5928018506    Vev: ALPHA-VET KFT.    File név: BA00001663    Egyedi sorszám: BA000001837 17 másolat  
 Szállító: Bayer Állat gyógyászati Üzletág    Oldal/Lap 3 / 1    Anyaglap: 500144305  
 Az eredetivel megegyez elektronikus másolat a(z):  
 Dr. Gacsályi Panna min.bizt.gyógyszerész által küldve.    Nyomtatás dátuma: 2015.10.14    **CertEx v 3.03a**



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 2 of 3 Date: 2015-04-08
Material: 84509604 Your material:		BAYTRIL 0.5% ORAL SOLUTION 100 ML BOTTLE X 100 ML BAYTRIL 0.5% ORAL SOLUTION 100 ML		
Batch:	KP0A8ZD	Country: Hungary		Delivery number: 104580196
Date of manufacture:	2015-01-08	Order number: 4193303		
Expiry date:	2018-01-31			
From material:	00865966	Insp. instruction:	T.02.02 - 7	
Inspection lot:	040001385764	Specification:	T.02.28 - 10	
Inspection	Acceptance criterion	UoM	Result	
Escherichia coli	Absence in 1 g		*)	

Diszpó: 5928018506    Vev: ALPHA-VET KFT.    File név: BA00001663    Egyedi sorszám: BA000001837 17 másolat  
 Szállító: Bayer Állat gyógyászati Üzletág    Oldal/Lap 3 / 2    Anyaglap: 500144305  
 Az eredetivel megegyez elektronikus másolat a(z):  
 Dr. Gacsályi Panna min.bízt.gyógyszerész által küldve.    Nyomtatás dátuma: 2015.10.14    **CertEx v 3.03a**



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Material: 84509604 Your material:		BAYTRIL 0.5% ORAL SOLUTION 100 ML BOTTLE X 100 ML BAYTRIL 0.5% ORAL SOLUTION 100 ML			
Batch: KP0A8ZD Date of manufacture: 2015-01-08 Expiry date: 2018-01-31		Country: Hungary Delivery number: 104580196 Order number: 4193303			
From material: 06065236 Batch: KP0A48N Inspection lot: 040001394949		BAYTRIL LOESG 0,5% ORAL 100 ML		Insp. instruction: ---- Specification: ----	
Inspection	Acceptance criterion	UoM	Result		
Fill volume	min. 100	ml	102		

\*) Test is carried out on spot-check basis. However we confirm compliance with the inspection and requirements also for this batch.

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:

2015-04-08 03:40:44 p.m. CET ( UTC + 1 hour )

Inspection lot:

040001420290

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