Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	**Certificate of Analysis**	Page: 1 of 2 Date: 2015-08-18
Material: 84348287 Your material:	BAYTRIL 10% ORAL SOLUTION 1000 ML PLASTIC BOTTLE X 1000 ML BAYTRIL 10% ORAL SOLUTION 1000 ML	
Batch: KP0AJ59 Date of manufacture: 2015-04-29 Expiry date: 2019-04-30		Country: Hungary Delivery number: 105686942 Order number: 4891557
From material: 81571082 Batch: KP0ABB1 Inspection lot: 040001432540	BAYTRIL ORALE LOESUNG 10% G/V (XINHUA)	Insp. instruction: T.02.02 - 8 Specification: T.02.28 - 12

Inspection	Acceptance criterion	UoM	Result
Material (visual)	Solution		solution
Colour (visual)	yellowish		yellowish
Clarity (visual)	clear		clear
Identity	must comply		complies
Relative density	1.035 - 1.045		1.039
pH-value	11.0 - 12.0		11.9
Solution (1:1000)	clear, clourless		complies
Benzyl alcohol	1.26 - 1.54	g/hml	1.35
Assay	9.5 - 10.5	g/hml	10.0
Ciprofloxacin	max. 0.5	%	0.1
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	*)

Bayer HealthCare

KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis	Page: 2 of 2 Date: 2015-08-18
Material: 84348287 Your material:	BAYTRIL 10% ORAL SOLUTION 1000 ML PLASTIC BOTTLE X 1000 ML BAYTRIL 10% ORAL SOLUTION 1000 ML	
Batch: KP0AJ59 Date of manufacture: 2015-04-29 Expiry date: 2019-04-30		Country: Hungary Delivery number: 105686942 Order number: 4891557
From material: 81571082		
Inspection lot: 040001432540		Insp. instruction: T.02.02 - 8 Specification: T.02.28 - 12

Inspection	Acceptance criterion	UoM	Result
Escherichia coli	Absence in 1 g		*)

*) 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

This Certificate of Analysis was automatically printed.