



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2014-01-13
Material: 81577927 Your Material:		BAYTRIL 0.5% ORAL SOLUTION 100ML BOTTLE X 100 ML BAYTRIL 0.5% ORAL SOLUTION 100ML		
Batch:	KP097TV	Country: Hungary		
Date of manufacture:	2013-03-14	Delivery number: 101606477		
Expiry date:	2016-03-31	Order number: 1965193		
From Material:	00865966	BAYTRIL LOESG 0,5% G/V ORAL		
Batch:	KP08HRH	Insp. instruction:	T.02.02 - 6	
Inspection lot:	040001086246	Specification:	T.02.01 - 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	9.5 - 11.5		11.1	
Benzyl alcohol	1.12 - 1.54	g/hml	1.28	
Assay	0.45 - 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	< 50	
Total combined yeast/mould count (TYMC)	max. 10	CFU/g	< 10	
Escherichia coli	Absence in 1 g		not detectable in 1 g	



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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 - Dr. Amann - QP

This Certificate of Analysis was automatically printed.