



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2013-10-08
Material: 81592470 Your Material:		BAYTRIL 10% INJ. 100 ML GLASS BOTTLES X 100 ML BAYTRIL 10% INJ. 100 ML		
Batch:	KP090NC	Country: Hungary		
Date of manufacture:	2013-06-30	Delivery number: 101221371		
Expiry date:	2016-06-30	Order number: 1880618		
From Material:	06713882	BAYTRIL INJ SOL 10% M/V 100ML		
Batch:	KP08XL0	Insp. instruction:	T.02.02 - 6	
Inspection lot:	010002252904	Specification:	T.02.01 - 6	
Inspection	Acceptance criterion	UoM.	Result	
Formulation	Solution		solution	
Clarity	clear		clear	
Colour (visual)	light-yellow		light yellow	
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	101.9	
Purity (visual)	free from visible impurities		free from visible impurities	
Relative density	1.032 - 1.037		1.034	
pH-value	10.5 - 12.0		11.5	
n-Butanol	2.70 - 3.30	g/hml	2.92	
Assay	9.5 - 10.5	g/hml	9.9	
Any unspecified degradation product	max. 0.3	%	0.1	
Total unspec.degradation products	max. 1.0	%	0.1	
Sum of all impurities	max. 1.5	%	0.3	
Ciprofloxacin	max. 1.0	%	0.1	



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Inspection	Acceptance criterion	UoM.	Result		
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 - Dr. Fröhlich - QP

This Certificate of Analysis was automatically printed.