



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany	Certificate of Analysis		Page: 1 of 2 Date: 2014-01-13
Material: 81592470 Your Material:	BAYTRIL 10% INJ. 100 ML GLASS BOTTLES X 100 ML BAYTRIL 10% INJ. 100 ML		
Batch: KP095R1 Date of manufacture: 2013-09-15 Expiry date: 2016-09-30	Country: Hungary Delivery number: 101606455 Order number: 2158103		
From Material: 06713882 Batch: KP0941V Inspection lot: 010002281633	BAYTRIL INJ SOL 10% M/V 100ML		Insp. instruction: T.02.02 - 6 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	101.7
Purity (visual)	free from visible impurities		free from visible impurities
Relative density	1.032 - 1.037		1.034
pH-value	10.5 - 12.0		11.4
n-Butanol	2.70 - 3.30	g/hml	2.89
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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From Material:	06713882	BAYTRIL INJ SOL 10% M/V 100ML		
Batch:	KP0941V	Insp. instruction:	T.02.02 - 6	
Inspection lot:	010002281633	Specification:	T.02.01 - 6	
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. Amann - QP

This Certificate of Analysis was automatically printed.