



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		<b>Certificate of Analysis</b>	Page: 1 of 2 Date: 2012-04-05
Material: 81595667 Your Material:		BAYTRIL INJEKT LOES 5% 100 ML BOTTLE X 100 CC BAYTRIL INJEKT LOES 5% 100 CC	
Batch:	KP07SU5	Country: Hungary	
Date of manufacture:	2011-10-19	Delivery number: 82689705	
Expiry date:	2014-10-31	Order number: 919036	
From Material:	06713866	BAYTRIL INJ SOL 5% M/V 100ML	
Batch:	KP07L9T		Insp. instruction: T.02.02 - 6
Inspection lot:	010001946105		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	101.2
Purity (visual)	free from visible impurities		free from visible impurities
Relative density	1.011 - 1.017		1.016
pH-value	10.5 - 12.0		11.4
n-Butanol	2.70 - 3.30	g/hml	2.89
Assay	4.75 - 5.25	g/hml	5.06
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	%	0.2



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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. Amann -QP

This Certificate of Analysis was automatically printed.