



KVP Pharma+Veterinär Produkte GmbH Kiel, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2014-05-09
Material: 81211906 Your Material:		CATOSAL 10% 100ML GLASS BOTTLE X 100 ML CATOSAL 10% 100ML		
Batch:	KP09D3R	Country: Hungary		
Date of manufacture:	2013-12-02	Delivery number: 102348383		
Expiry date:	2016-12-31	Order number: 2343065		
From Material:	06355609	BUTA+VITB12 IV 10+0,005 100ML		
Batch:	KP09C9F	Insp. instruction:	T.02.02 - 2	
Inspection lot:	010002325683	Specification:	T.02.01 - 3	
Inspection	Acceptance criterion	UoM.	Result	
Formulation	Solution		solution	
Colour (visual)	pink-coloured		pink	
Clarity	clear		clear	
Identity (Butaphosphane)	must comply		complies	
Identity vitamin B 12	must comply		complies	
Identity (n-Butanol)	must comply		complies	
Extractable volume	min.100 ml		>100	
Purity (visual)	must comply		complies	
Density	1.007 - 1.013	g/ml	1.011	
pH-value	5.0 - 6.0		5.6	
n-Butanol	2.7 - 3.3	g/hml	3.0	
Assay butaphosphane	9.5 - 10.5	g/hml	10.1	
Assay vitamin B 12	4.5 - 5.8	mg/hml	5.6	
Oxa-Butaphosphane	max. 1.0	%	0.1	
Any unspecified degradation product	max. 1.0	%	< 0.3	
Sum of all degradation products	max. 1.7	%	0.4	



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Inspection	Acceptance criterion	UoM.	Result		
Sterility	sterile		sterile		
Endotoxins	<89.29 E.U./ml		<3.84		

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.