

Certificate of Analysis



Name of the product	: Cyclo Spray		
Product number	: 97063004	Packaging	: 211 ml
Batch number	: 1510576	Date of analysis	: 30-11-2015
Manufacturing date	: 10-2015	CoA version	: SC-LAB97063004.5.0
Expiry date	: 10-2018	Destination	: Hungary
Batch number internal	: 944862		

DETERMINATIONS	SPECIFICATIONS	RESULTS
CHARACTERS	Blue suspension	Blue suspension
ODOUR	Characteristic odour of IPA	Characteristic odour of IPA
NETT FILL WEIGHT (g)	126.8 – 134.7	131.6
PARTICLE SIZE DISTRIBUTION (%)	$\geq 80\% < 100 \mu\text{m}$ $\geq 45\% < 50 \mu\text{m}$ $\geq 15\% < 20 \mu\text{m}$	100 95 73
PRESSURE TESTING (bar)	2.5 - 3.5	3.2
LEAKAGE TESTING (%/year)	< 3.5	0.2
DELIVERY RATE (g/s)	0.9 -1.6	1.2
RESUSPENDABILITY (%)	≥ 90	96.1
MICROBIOLOGICAL QUALITY	Ph.Eur.,5.1.4, Cat.2	Ph.Eur.,5.1.4, Cat.2
IDENTIFICATION OF		
Patent blue V	Positive	Positive
Chlortetracycline HCl	Positive	Positive
PACKAGING & LABELLING	Conform instructions	Conform instructions
ASSAY		
Chlortetracycline HCl (g/container)	3.05 - 3.37	3.27

Conclusion : Conform specifications.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Jeroen Van den Brande

07 APR 2016

Qualified Person

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