


Certificate of Analysis

Name of the product : Cyclo Spray

Product number : 97063004
Batch number : 1708762
Manufacturing date : 08-2017
Expiry date : 08-2020
Batch number internal : 958304

Packaging : 211 ml
Date of analysis : 02-10-2017
CoA version : SC-LAB97063004.5.0
Destination : Hungary

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	132.1
PARTICLE SIZE DISTRIBUTION (%)	≥80% < 100 µm ≥45% < 50 µm ≥15% < 20 µm	100 96 79
PRESSURE TESTING (bar)	2.5 - 3.5	3.0
LEAKAGE TESTING (%/year)	< 3.5	0.2
DELIVERY RATE (g/s)	0.9 -1.6	1.2
RESUSPENDABILITY (%)	≥ 90	98
MICROBIOLOGICAL QUALITY	Ph.Eur.,5.1.4, Cat.2	Ph.Eur.,5.1.4, Cat.2
IDENTIFICATION OF Patent blue V Chlortetracycline HCl	Positive Positive	Positive Positive
PACKAGING & LABELLING	Conform instructions	Conform instructions Stefan van Roosmalen
ASSAY Chlortetracycline HCl (g/container)	3.05 - 3.37	3.29  27 OKT 2017

Conclusion : Conform specifications.

Qualified Person

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.