

Certificate of Analysis

Name of the product : Cyclospray 78,6 mg/g

Product number : 97063034
Batch number : 1802186
Manufacturing date : 02-2018
Expiry date : 02-2021
Batch number internal : 961564

Packaging : 200 ml
Date of analysis : 05-03-2018
CoA version : SC-LAB97063034.1.0
Destination : Romania

DETERMINATIONS	SPECIFICATIONS	RESULTS
CHARACTERS	Blue suspension	Blue suspension
NETT FILL WEIGHT (g)	126.8 - 134.7	132.0
RELATIVE DENSITY	0.800 - 0.830	0.826
PARTICLE SIZE DISTRIBUTION (%)	$\geq 80\% < 100 \mu\text{m}$ $\geq 45\% < 50 \mu\text{m}$ $\geq 15\% < 20 \mu\text{m}$	100 90 70
PRESSURE TESTING (bar)	2.5 - 3.5	3.0
LEAKAGE TESTING (%/year)	< 3.5	0.0
DELIVERY RATE (g/s)	1.1 - 1.6	1.2
SPRAY PATTERN	Complies to reference	Complies to reference
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 Average (g/container)	3.05 - 3.35	3.26
Chlortetracycline HCl Individual (g/container)	2.89 - 3.53	3.17 - 3.34

Conclusion : Conform specifications.

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination

country/countries

EUROFET B.V. (EUROFET PH)
P.O. Box 179, 5530 AD Bladel, the Netherlands, Handelsweg 25, 5531 AE Bladel, the Netherlands.

Phone +31 (0)497 54 43 00, Fax +31 (0)497 54 43 02, www.dechra.com

BNP Paribas, IBAN: NL26 BNPA 0227 0934 09, BIC: BNPA NL2A, VAT: NL 0075.03.401.B01

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