

Certificate of Analysis

23 MEI 2018

Qualified Person

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

Product number : 97063034
Batch number : 1802185
Manufacturing date : 02-2018
Expiry date : 02-2021
Batch number internal : 961563

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	132.3
RELATIVE DENSITY	0.800 - 0.830	0.826
PARTICLE SIZE DISTRIBUTION (%)	≥80% < 100 µm ≥45% < 50 µm ≥15% < 20 µm	99 88 67
PRESSURE TESTING (bar)	2.5 - 3.5	3.1
LEAKAGE TESTING (%/year)	< 3.5	0.2
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	3.21 - 3.30

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