

Certificate of Analysis

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

Product number : 97061018

Batch number : 1906909

Manufacturing date : 06-2019

Expiry date : 06-2022

Batch number internal : 969974

Packaging : 200 ml

Date of analysis : 15-07-2019

CoA version : SC-LAB97061018.1.0

Destination : Romania

DETERMINATIONS	SPECIFICATIONS	RESULTS
CHARACTERS	Blue suspension	Blue suspension
NETT FILL WEIGHT (g)	126.8 - 134.7	131.7
RELATIVE DENSITY	0.800 - 0.830	0.825
PARTICLE SIZE DISTRIBUTION (%)	$\geq 80\% < 100 \mu\text{m}$	100
	$\geq 45\% < 50 \mu\text{m}$	94
	$\geq 15\% < 20 \mu\text{m}$	71
PRESSURE TESTING (bar)	2.5 - 3.5	3.1
LEAKAGE TESTING (%/year)	< 3.5	0.2
DELIVERY RATE (g/s)	1.0 - 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 Chlortetracycline HCl	Positive	Positive
	Positive	Positive
PACKAGING & LABELLING	Conform instructions	Conform instructions
ASSAY		
Chlortetracycline HCl Average (g/container)	3.05 - 3.35	3.21
Chlortetracycline HCl Individual (g/container)	2.89 - 3.53	3.17-3.25

Paul Vondracek

17 JUL 2019

Qualified Person

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.

with the GMP requirements of the EU and with the requirements of the country/countries

© 2011 by the author(s). All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or by any information storage or retrieval system, without permission in writing from the publisher, Cambridge University Press.

Marketing Authorisation(s) of the destination

Dechra