

FIRST OFF



Diversey Europe Operations BV
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CERTIFICATE OF ANALYSIS

Date: 21.10.2019

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP19294, 47912
Production Date	21/10/2019
Expiration Date	EXP 21/10/2021

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (neat solution)	DM001	9.0	12.5	11.3
Specific Gravity (20°C)	DM004	1.004	1.020	1.009
Potential Chlorine Dioxide (ppm)		100	180	141.75

On behalf of Diversey site Quality Manager	Name :	Harabudo Partys
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of Issuing : November 24 th 2017
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CERTIFICATE OF ANALYSIS

Date: 21.10.2019

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP19294, 47912
Production Date	21/10/2019
Expiration Date	EXP 21/10/2021

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		clear colourless liquid
pH (neat solution)	DM001	1.5	2.5	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.015

On behalf of Diversey site Quality Manager	Name :	Harshada Paryas
	Position	Quality Control Inspector

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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-4940A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO47913	8	Case

Validation Reference Number: 4725

Processing Run Start Date: 01-Sep-19 10:01 PM

Processing Run End Date: 02-Sep-19 05:05 AM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	28.4
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	35.1

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

Items irradiated under WO47913 will be used in finished batch Fmp19294 47912

Olga Kirchner

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Bi-Spore Activator

Sample Description: Sample Code: Fmp19294 47912

Lucideon Sample Number: (195925)-45967

Lucideon Report Number: (195925)-45967/MFEP

Issue Number: 1

Date Logged: 28-Oct-2019

Order Number: PO34186

Date Reported: 11-Dec-2019

Date(s) of Test(s): 27-Nov-2019 to 11-Dec-2019

Sterility Testing

Membrane Filtration EP

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report

NB Boot 11-Dec-19

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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Lucideon is the trading name of Lucideon Limited. Registered in England No. 1960455.

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Bi-Spore Base

Sample Description: Sample Code: Fmp19294 47912

Lucideon Sample Number: (195925)-45968

Lucideon Report Number: (195925)-45968/MFEP

Issue Number: 1

Date Logged: 28-Oct-2019

Order Number: PO34186

Date Reported: 11-Dec-2019

Date(s) of Test(s): 27-Nov-2019 to 11-Dec-2019

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

Natalie Boot 11-Dec-19

Mrs Natalie Boot

Senior Business Support Assistant

Page 1 of 1

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