



Diversey Europe Operations BV
Maarssebroeksewijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 15 March 2021

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP21074 51395
Production Date	15/03/2021
Expiration Date	EXP 15/03/2023

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	11.5
Specific Gravity (20°C)	DM004	1.004	1.020	1.009
Potential Chlorine Dioxide (ppm)	N/A	100	180	141.75

On behalf of Diversey site Quality Manager	Name :	Justyna Staron Angellka Partynska
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
--------------	--------------	--



Diversey Europe BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 8427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 15 March 2021

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26		
Product Code	7514852		
Batch Number	FMP21074	51395	
Production Date	15/03/2021		
Expiration Date	EXP 15/03/2023		

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	2.0
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	Justyna Staron Angelika Partynska
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of Issuing : November 24 th 2017
--------------	--------------	--

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-16875A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO51394	8	Case
Validation Reference Number: 4725			

Processing Run Start Date: 05-Feb-21 11:00 AM

Processing Run End Date: 05-Feb-21 04:33 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	26.8
Reference Dose Range (kGy):	30.2 - 39.2	Calculated Max Dose (kGy):	33.6

PO Number: 37355

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

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 WO51394 will be used in finished batch FMP21074 51395.

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: FMP21074 51395

Lucideon Sample Number: UK211252-8633

Lucideon Report Number: UK211252-8633/MFEP

Issue Number: 1

Date Logged: 23-Mar-2021

Order Number: PO 37717

Date Reported: 12-Apr-2021

Date(s) of Test(s): 25-Mar-2021 to 08-Apr-2021

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

NCB001 12-APR-21

Mrs Natalie Boot

Business Support Administrator

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

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 Base

Sample Description: Sample Code: FMP21074 51395

Lucideon Sample Number: UK211252-8634

Lucideon Report Number: UK211252-8634/MFEP

Issue Number: 1

Date Logged: 23-Mar-2021

Order Number: PO 37717

Date Reported: 12-Apr-2021

Date(s) of Test(s): 25-Mar-2021 to 08-Apr-2021

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 12 APR-21
Mrs Natalie Boot

Business Support Administrator

Page 1 of 1

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the accuracy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to misrepresentation of the results or their implications.

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

Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com