

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 25 09 2020

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26		
Product Code	7514852		
Batch Number	FHP 20269 50318		
Production Date	25 09 2020		
Expiration Date	Exp 25/09/2022		

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	
The state of the s		Lower	- Upper		
Appearance	Visual	Clear Colourless Liquid		Clear Colourles	
pH (neat solution)	DM001	9.0	12.5	11.5	
Specific Gravity (20°C)	DM004	1.004	1.020	1-008	
Potential Chlorine Dioxide (ppm)		100	180	151.875 ppm	

liquid

On behalf of Diversey site Quality Manager	Name:	A -Bonys Manologida
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



Diversey Europe BV Maarasenbroeksedijk 2 3542 DN Utrecht The Netherlands

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

CERTIFICATE OF ANALYSIS

Date: 18/09/2020

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26		
Product Code	7514852		
Batch Number	FMP 20269 50318		
Production Date	25 09 2020		
Expiration Date	Exp 25/09/ 2022		

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 Colour	less Liquid	clear clausess !
pH (neat solution)	DM001	1.5	2.5	1.9
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name:	A Boys, & slavar
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template Version : 02	Date of issuing: November 24" 2017
---------------------------	------------------------------------

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-13312A

Product CodeLot NumberQuantityUOMBI-SP B3 COMPONENTS DV4725WO503178 Case

Validation Reference Number: 4725

Processing Run Start Date: 07-Sep-20 12:35 AM
Processing Run End Date: 07-Sep-20 06:41 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 28.2

Reference Dose Range (kGy): 30.2-39.2 Calculated Max Dose (kGy): 35.4

PO Number: 36309

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 WO50317 will be used in finished batch Fmp20269 50318.

Olga Kirchner

Rel Date: 08/13/2018

Document ID: 59378

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Bi-Spore Base

Sample Description:

Sample Code: Fmp20269 50318

Lucideon Sample Number: UK204037-28247

Lucideon Report Number: UK204037-28247/MFEP

Issue Number:

Date Logged:

06-Oct-2020

Order Number:

PO 36555

Date Reported:

30-Oct-2020

Date(s) of Test(s):

14-Oct-2020 to 28-Oct-2020

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



Mrs Andrea Saunders

Business Support Assistant

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Bi-Spore Activator

Sample Description:

Sample Code: Fmp20269 50318

Lucideon Sample Number: UK204037-28246

Lucideon Report Number: UK204037-28246/MFEP

Issue Number:

Date Logged:

06-Oct-2020

Order Number:

PO 36555

Date Reported:

30-Oct-2020

Date(s) of Test(s):

14-Oct-2020 to 28-Oct-2020

Sterility Testing

Membrane Filtration EP

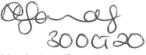
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



Mrs Andrea Saunders

Business Support Assistant

Lucideon Limited

Stoke-on-Trent