



Diversey Europe Operations BV
Maarssebroeksedijk 2
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CERTIFICATE OF ANALYSIS

Date: 18/12/2018

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP18352 46228
Production Date	18.12.2018
Expiration Date	EXP 18/12/2020

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	11.8
Specific Gravity (20°C)	DM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	141.75

On behalf of Diversey site Quality Manager	Name :	J. Staan, P. J. J. J.
	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: 19.12.2018

Product Name	CLEARLENs BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FNP18352, 46228
Production Date	18.12.2018
Expiration Date	EXP 18/12/2020

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	2.3
Specific Gravity (20°C)	DM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	J. Slawon, Pautyska
	Position	Quality Control Inspector

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

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 08 Jan 2019
Date Tested: 21 Jan 2019
Date Test Completed: 04 Feb 2019
Purchase Order: 32357

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046598/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 08/01/2019
Test Article: BI-Spore (Activator)
Sample Code: FMP18352 46228
Batch Ref: 622519
Qty Received: 20 x 100mL Bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04-01

Approval is provided by Electronic Signature. Their name and position is shown below.

C/Moore MRSB

Date: 07 Feb 2019 08:13:38

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 08 Jan 2019
Date Tested: 21 Jan 2019
Date Test Completed: 04 Feb 2019
Purchase Order: 32357

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0046598/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 08/01/2019
Test Article: Bi-Spore (Base)
Sample Code: FMP18352 46228
Batch Ref: 622518
Qty Received: 20 x 100mL Bottles

Test	Method Item	Result
Sterility Test by Membrane Filtration (Steritest) Method	MM107/00	Pass
Growth in Tryptone Soya Broth at 20-25°C after 14 days	MM107/01	No growth in two broths
Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days	MM107/02	No growth in two broths
Volume Tested	MM107/05	20 x 50 mL
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 41 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05-01

Approval is provided by Electronic Signature. Their name and position is shown below.

C Biol MR3B

Date: 07 Feb 2019 08:13:38

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-889A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BI-SP B3 COMPONENTS DV4725	WO46229	8	Case

Validation Reference Number: 4725

PO Number: PO32209

Processing Run Start Date: 08-Dec-18 05:33 PM

Processing Run End Date: 08-Dec-18 11:36 PM

Specified Dose Range (kGy):	25.0 - 40.0	Calculated Min Dose (kGy):	27.4
Reference Dose Range (kGy):	30.2- 39.2	Calculated Max Dose (kGy):	35.8

Other Information

WO46229, 1 PLT

Signature Manifest

Reviewed and E-Signed By: Mark Morse (QA Officer)

Date/Time E-Signed: 2018-12-10 11:57 AM

Document Content Revision: 1

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 WO46229, will be used in finished product batch FMP18352 46228

C Pascoe

STERIS: Gamma Dosimetry Record
FLEXIBLE MEDICAL PACKAGING LTD (8245)

Run ID: 2173-889A

Irradiator / Method: IR-150 Hydraulic Irradiator - ON-STD

Carrier-Seq	Coordinate	Batch (Cal Date)	Spectro S/N	Micro S/N	Absorbance	Thickness	Final Dose (kGy)	Comment
1-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.859	2.8674	35.1	
4-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.890	2.9846	34.8	
8-1	D-Ref	PL (2018-03-20)	5A3P011003	MX 700993	0.796	2.7313	33.1	

Minimum Reference Dose for Record (kGy): 33.1
Maximum Reference Dose for Record (kGy): 35.1

Last Dosimeter Measurement Date: 2018-12-09 04:50 AM

Signature Manifest

Prepared By: Marcin Ladwik (Operator)

Date/Time E-Signed: 2018-12-09 04:50 AM

Document Content Revision: 1

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

Comment Legend: OUT = Calculated Dose Outside Allowable Limits Provided By Process Specification

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Last Revised In Rel 2.0.0.0

Rel Date: 08/13/2018

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