

Activator
First of



Diversey Europe Operations BV
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CERTIFICATE OF ANALYSIS

Date: 25/06/2018

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 18176 45357
Production Date	25/06/2018
Expiration Date	EXP 25/06/2020

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	11.9
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	151.875ppm

On behalf of Diversey site Quality Manager	Name :	Panayiotis Karaburda
	Position	Quality Control Inspector

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

Date: 26.06.2018

Product Name	CLEARLENs BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 18176 45357
Production Date	25/06/2018
Expiration Date	EXP 25/06/2020

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	2.4
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	U. Harabuda, P. Polyzis
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 21-May-2018

UK33S12104781-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

Flexible Medical Packaging Ltd
Unit 8, White Cross Ind Estate
Hightown
Lancaster
Lancashire LA1 4XS
UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106825
Customer Reference Number:	P031016
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO45392, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	18-May-2018 08:30
Reference Dose Range kGy:	31.7 - 33.4
Calculated Minimum Dose kGy:	26.3
Calculated Maximum Dose kGy:	34.1

Items irradiated under WO45392, will be used in finished product batch FMP18176 45357.

C Pascoe

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



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: 03 Jul 2018
Date Tested: 17 Jul 2018
Date Test Completed: 31 Jul 2018
Purchase Order: 31307

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0043499/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 03/07/2018
Test Article: Bi-Spore Activator
Sample Code: FMP1817645357
Batch Ref: 600928
Qty Received: 10 x 100mL Bottles

Test	Method Item	Result	Specification
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	

Comments

11 x Bottles of Bi-Spore Activator received 12/07/18 Batch: 600928, Sample Code: FMP1817645357. Allocated to LR 0043499/2A.

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

C.Boi. ANSB

Date: 01 Aug 2018 16:17:13

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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: 03 Jul 2018
Date Tested: 17 Jul 2018
Date Test Completed: 31 Jul 2018
Purchase Order: 31307

CERTIFICATE OF ANALYSIS


Laboratory Reference Number: 0043499/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 03/07/2018
Test Article: Bi-Spore Base
Sample Code: FMP1817645357
Batch Ref: 610100
Qty Received: 10 x 100mL Bottles

Test	Method Item	Result	Specification
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	

Comments

11 x Bottles of Bi-Spore Base received 12/07/18 Batch: 610100, Sample Code: FMP1817645357.
Allocated to LR 0043499/1A.

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

 CBio: MMSB

Date: 01 Aug 2018 16:17:13

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology