



Diversey Europe Operations BV

 Maarssenbroeksedijk 2
 3542 DN Utrecht
 The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 16/11/2016

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 16 321 41526
Production Date	16/11/2016
Expiration Date	EXP 16/11/2018

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 (100% 20°C)	JDM001	1.5	2.5	1.9
Specific Gravity (20°C)	JDM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	<i>Bertus de Vries</i>
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Base	Version : 01	Date of issuing : September 27 th 2012
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Goods in



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CERTIFICATE OF ANALYSIS

Date: 16/11/2016

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 16321 41526
Production Date	16/11/2016
Expiration Date	EXP 16/11/2018

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 (100% 20°C)	JDM001	9.0	12.5	12.5
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	159 ppm

On behalf of Diversey site Quality Manager	Name :	Patyisha, H. Chin
	Position	Quality Control Inspector

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COA Bi-Spore Activator	Version : 01	Date of issuing : October 1 st 2012
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FIRST OFF



Diversey Europe Operations BV

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CERTIFICATE OF ANALYSIS

Date: 16/11/2016

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 16321 41526
Production Date	16/11/2016
Expiration Date	EXP 16/11/2018

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 (100% 20°C)	JDM001	9.0	12.5	12.2
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	145ppm

On behalf of Diversey site Quality Manager	Name :	Paulysko, H. [Signature]
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator	Version : 01	Date of issuing : October 1 st 2012
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Diversey

Tel. +31 (0)30 247 6427

Date: 16/11/2016

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

On behalf of Diversey site Quality Manager	Name :	<i>H. M. P. Parry</i>
	Position	Quality Control Inspector

Date of issuing : September 27th 2012

<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 19-Oct-2016

UK33S11727974-2-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 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:	P027466
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	W041525, 1PLT

Irradiation Data

Date and Time of Irradiation:	19-Oct-2016 17:44
Reference Dose Range kGy:	33.4 - 33.5
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	34.2

Items irradiated under W041525 will be used in finished product FMP16321 41526.

Irradiation Release Authorised By Synergy Health plc

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: 24 Nov 2016
Date Tested: 29 Nov 2016
Date Test Completed: 13 Dec 2016
Purchase Order: 27784

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0032438/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 24/11/2016
Test Article: Bi-Spore Base
Sample Code: FMP16321 41526
Batch Ref: 552908
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 8.0 2.6.1. USP 39 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

Date: 14 Dec 2016 13:06:00

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 24 Nov 2016
Date Tested: 29 Nov 2016
Date Test Completed: 13 Dec 2016
Purchase Order: 27784

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0032438/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 24/11/2016
Test Article: Bi-Spore Activator
Sample Code: FMP16321 41526
Batch Ref: 552910
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 8.0 2.6.1. USP 39 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

Date: 14 Dec 2016 13:06:00

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology