



Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 5/12/14

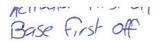
Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26		
Product Code	7514852		
Batch Number	FMP14337 36641		
Production Date	12/2014		
Expiration Date	06/2016		

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

	Lower -	Upper	
Visual		요하는 없는 없이라면 하게 되고 그리	Cler Colouriess
JDM001	1.5	2.5	1.6
JDM004	1.010	1.030	1.018
-	JDM001	Visual Clear Co Liq JDM001 1.5	Visual Clear Colourless Liquid JDM001 1.5 2.5

On hehalf of Diverses site	Name:	Charle, Olpa Kinchin
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued electronical	ly does not bear a signature	
COA Bi-Spore Base	Version: 01	Date of issuing : September 27th 2012





Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 3/12/14

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP14337 36641
Production Date	12/2014
Expiration Date	06/2016

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

Test	Test Method	Lower -	nits Upper	Results
Appearance	Visual		olourless Juid	Cicar colouries
pH (100% 20°C)	JDM001	9.0	12.5	12.2
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	162PPM

On bahalf of Diversity	Name:	More Olpa Kinchno
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 09-Nov-2014

UK32S11273402-1-1

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

EN ISO 11137-1:2006 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:	1002735
Customer Reference Number:	P023226
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.1624
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/N W036642 THUR 06.11.14 2 PLTS LOT 1

Irradiation Data		
Date and Time of Irradiation:	09-Nov-2014 16:59	
Reference Dose Range kGy:	34.0 - 34.3	
Calculated Minimum Dose kGy:	28.2	
Calculated Maximum Dose kGy:	35.9	

Items irradiated under WO36642 will be used in finished product batch code FMP14337 36641

[Gaugne 11.12.14



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Fax:

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA14XS

Date Received:

12 Dec 2014

Date Tested:

19 Dec 2014

Date Test Completed:

02 Jan 2015

Purchase Order:

23448

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0020295/1

Test Required:

Sterility Test by Membrane Filtration (Steritest)

Date Received:

12/12/2014

Test Article:

Bi-Spore Solutions Activator

Sample Code:

479616

Batch Ref: **Qty Received:** FMP14337 36641 20 x 50mL 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
Product Standard Data Sheet	FG047/psd	FM04

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

Sur Wood

Date: 05 Jan 2015 16:18:29

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0020295

Certificate of Analysis - OSMM

Print Number: P0024798

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mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

12 Dec 2014

Date Tested:

19 Dec 2014

Date Test Completed:

02 Jan 2015

Purchase Order:

23448

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0020295/2

Test Required:

Sterility Test by Membrane Filtration (Steritest)

Date Received:

12/12/2014

Test Article:

Bi-Spore Solutions Base

Sample Code:

474717

Batch Ref: Qty Received: FMP14337 36641 20 x 50mL 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 Product Standard Data Sheet	MM107/05 FG047/psd	20 x 50 mL FM05

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

Sun Load.

Date: 05 Jan 2015 16:18:29

Mrs S.L. Wood

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0020295

Certificate of Analysis - OSMM

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Page 1 of 1

ISO 17025 GLP GMP FDA

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