

Activator first off
Base first off



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 6/2/15

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7518162
Batch Number	FMP15040 37631
Production Date	02/2015
Expiration Date	02/2017

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	11.9
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	145.125 ppm

On behalf of Diversey site Quality Manager	Name :	<i>M. O. Kinnear</i>
	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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3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 10/2/15

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7518162
Batch Number	FMP15040 37631
Production Date	02/2015
Expiration Date	02/2017

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	1.7
Specific Gravity (20°C)	JDM004	1.010	1.030	1.014

On behalf of Diversey site Quality Manager	Name :	<i>Chris O. Kirchner</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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 01-Feb-2015

UK32S11320748-1-1

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:	P023691
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 W037630 THUR 29.01.2015 2 PLTS

Irradiation Data

Date and Time of Irradiation:	01-Feb-2015 18:45
Reference Dose Range kGy:	33.7 - 33.8
Calculated Minimum Dose kGy:	27.9
Calculated Maximum Dose kGy:	35.3

Items irradiated under W037630 will be used in finished product batch code FMP15040 37631 *E. Gaughin 17.02.15*

Irradiation Release Authorised By Synergy Health plc

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

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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: 18 Feb 2015
Date Tested: 05 Mar 2015
Date Test Completed: 19 Mar 2015
Purchase Order: 23811

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0021246/1
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 18/02/2015
Test Article: Bi-Spore Solution (Activator)
Sample Code: 491596
Batch Ref: FMP 15040 37631
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
Product Standard Data Sheet	FG047/psd	FM04

Comments

Additional samples received on 02/03/2015

See NCR PHM 2015 043 and PHM 2015 054

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

Date: 20 Mar 2015 15:49:55

Mr K.A. Barker
Business Manager - Microbiology

Consignment: 0021246

Certificate of Analysis - OSMM

Print Number: P0026229

Page 1 of 1

ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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: 18 Feb 2015
Date Tested: 05 Mar 2015
Date Test Completed: 19 Mar 2015
Purchase Order: 23811

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0021246/2
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 18/02/2015
Test Article: Bi-Spore Solution (Base)
Sample Code: 491595
Batch Ref: FMP 15040 37631
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
Product Standard Data Sheet	FG047/psd	FM05

Comments

Additional samples received on 02/03/2015

See NCR PHM 2015 043 and PHM 2015 054

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