

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: 29/4/13

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7518162
Batch Number	FMP13117 33524
Production Date	04/2013
Expiration Date	04/2014

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	1.017

On behalf of Diversey site Quality Manager	Name :	<i>C. Piscoe, A. Motune</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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3542 DN Utrecht
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CERTIFICATE OF ANALYSIS

Date: 27/4/13

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7518162
Batch Number	FMP13117 33524
Production Date	04/2013
Expiration Date	04/2014

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	12.0
Specific Gravity (20°C)	JDM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	165.37ppm

On behalf of Diversey site Quality Manager	Name :	<i>C. M. A. M. M. A.</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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 17-Mar-2013

UK32S11009395-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products
 ISO 9001:2008 Quality Management System
 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

Customer Reference Number:	PO20056
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.0500
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/No. W033520 , 2 PLTS LOT 2 THURS 7.3.13
Shop Order Number:	S11009395-1-1
Synergy Health Sales Part Reference:	1002735

Irradiation Data

Date and Time of Irradiation:	17-Mar-2013 16:41
Reference Dose Range kGy:	34.6 - 35.1
Calculated Minimum Dose kGy:	26.3
Calculated Maximum Dose kGy:	36.4

Comments: Item Irradiated under W033520 will be used in finished product,
 FMP13117 33524

09.05.13. E-Gauger

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



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

Date Received: 03 May 2013
Date Tested: 09 May 2013
Date Test Completed: 23 May 2013
Purchase Order: P020347

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0010125/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 03/05/2013
Test Article: Bi Spore Activator
Sample Code: 436175
Batch Ref: FMP13117 33524
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

Test carried out according to current Pharmacopoeias.

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

Suz Wood

Date: 29 May 2013 16:25:25

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
Senior Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

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

Date Received: 03 May 2013
Date Tested: 09 May 2013
Date Test Completed: 23 May 2013
Purchase Order: P020347

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0010125/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 03/05/2013
Test Article: Bi Spore Base
Sample Code: 432030
Batch Ref: FMP13117 33524
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

Test carried out according to current Pharmacopoeias.

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

Suz Wood

Date: 29 May 2013 16:25:25

Mrs S.L. Wood, BSc (Hons), CBiol, MSB
 Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0010125

Certificate of Analysis - OSMM

Print Number: P0010810

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