

FRANCOIS...
Base first off with filter



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 19/9/13

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7518162
Batch Number	FMP13262 34576
Production Date	09/2013
Expiration Date	09/2014

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	11.3
Specific Gravity (20°C)	JDM004	1.004	1.020	1.009
Potential Chlorine Dioxide (ppm)		100	180	138.4

On behalf of Diversey site Quality Manager	Name :	A. Matura, <i>(signature)</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
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CERTIFICATE OF ANALYSIS

Date: 23/9/13

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7518162
Batch Number	FMP13262 34576
Production Date	09/2013
Expiration Date	09/2014

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. Pascoe</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: 06-Aug-2013

UK32S11041338-1-1

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:	PO20808
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:	FMP B/NO: WO34572 - THURS 01.08.13 2PLTS LOT 2

Irradiation Data

Date and Time of Irradiation:	06-Aug-2013 01:11
Reference Dose Range kGy:	34.4 - 35.3
Calculated Minimum Dose kGy:	26.1
Calculated Maximum Dose kGy:	36.6

The items irradiated under WO34572 will be used in finished product batch code FMP13262 34576

F. Garajon 26.09.13

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: 26 Sep 2013
Date Tested: 03 Oct 2013
Date Test Completed: 17 Oct 2013
Purchase Order: 21090

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0012518/1
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 26/09/2013
Test Article: Bi Spore Activator
Sample Code: FMP1326234576
Batch Ref: 436175
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

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

Sue Wood

Date: 21 Oct 2013 10:29:14

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology



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

Date Received: 26 Sep 2013
Date Tested: 03 Oct 2013
Date Test Completed: 17 Oct 2013
Purchase Order: 21090

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0012518/2
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 26/09/2013
Test Article: Bi Spore Base
Sample Code: FMP1326234576
Batch Ref: 432030
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

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

Sue Wood

Date: 21 Oct 2013 10:29:14

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology