



Diversey Europe Operations BV

 Maarssebroeksedijk 2
 3542 DN Utrecht
 The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 1.07.13

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 13 182 34345
Production Date	07/2013
Expiration Date	07/2014

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	12.2
Specific Gravity (20°C)	JDM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	165.37 ppm

On behalf of Diversey site Quality Manager	Name :	A. Motus, <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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FIRST OFF



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 2.07.13

Product Name	CLEARLENs BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 13 182 34345
Production Date	07/2013
Expiration Date	07/2014

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 :	A. Mathew, <i>cm</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: 19-Aug-2013

UK32S11026755-1-1

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:	P020515
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.WO34344 , 2 PLTS LOT 1 THURS 6.6.13

Irradiation Data

Date and Time of Irradiation:	11-Jun-2013 00:49
Reference Dose Range kGy:	34.0 - 35.4
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	36.8

Items irradiated under WO34344 will be used in finished product number FMP13182 34345

L. Gough 19.08.13

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



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

Date Received: 04 Jul 2013
Date Tested: 10 Jul 2013
Date Test Completed: 24 Jul 2013
Purchase Order: PO20654

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0011165/1
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 04/07/2013
Test Article: Bi Spore Activator
Sample Code: FMP13182 34345
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 is shown below.

Suz Wood

Date: 14 Aug 2013 15:15:02

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

Consignment: 0011165

Certificate of Analysis - OSMM

Print Number: P0012739

Page 1 of 1



Wickham Laboratories
contract analytical services

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www.wickhamlabs.co.uk

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

Date Received: 04 Jul 2013
Date Tested: 10 Jul 2013
Date Test Completed: 24 Jul 2013
Purchase Order: PO20654

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0011165/2
Test Required: Sterility Test by Membrane Filtration (Steritest)
Date Received: 04/07/2013
Test Article: BI Spore Base
Sample Code: FMP13182 34345
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 is shown below.

Date: 14 Aug 2013 15:15:02

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

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