


Diversey

Tel. +31 (0)30 247 6427

Date: 26.10.15

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

On behalf of Diversey site Quality Manager	Name :	
	Position	Quality Control Inspector

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: 26.10.2015

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP15293 38475
Production Date	20/10/2015
Expiration Date	20/10/2017

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	1.5
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	
	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: 13-Aug-2015

UK32S11442329-1-1

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:	P024874
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 WO38774 THUR 06 AUG 2015 2 PLTS LOT 2

Irradiation Data

Date and Time of Irradiation:	12-Aug-2015 19:07
Reference Dose Range kGy:	32.8 - 33.1
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	34.6

Items irradiated under WO38774 will be used in finished product batch code:FMP15293 38775

LGaughey 27.10.15

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

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

Date Received: 28 Oct 2015
Date Tested: 03 Nov 2015
Date Test Completed: 17 Nov 2015
Purchase Order: 25375

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025521/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 28/10/2015
Test Article: Bi-Spore
Sample Code: Base
Batch Ref: FMP15293 38775
Qty Received: 21 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 and position is shown below.

Date: 18 Nov 2015 15:54:25

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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

Date Received: 28 Oct 2015
Date Tested: 03 Nov 2015
Date Test Completed: 17 Nov 2015
Purchase Order: 25375

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025521/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 28/10/2015
Test Article: Bi-Spore
Sample Code: Activator
Batch Ref: FMP15293 38775
Qty Received: 21 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 and position is shown below.

Date: 18 Nov 2015 15:54:24

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology