



Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 8:09.15

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 15244, 38702
Production Date	01.09 2015
Expiration Date	EXP 01.09.2017

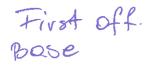
This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Lin	nits	Results
		Lower -	Upper	
Appearance	Visual	Clear Co	olourless	Clear Colourles
		Liq	juid	liquid
pH (100% 20°C)	JDM001	9.0	12.5	11.5
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)	, ,	100	180	155.25 ррт

0 1 1 10 00	Name:	Il. Allen Mahue
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator Version: 01 Date of issuing: October 1st 2012





Diversey Europe Operations BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 8,09.15

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515 828
Batch Number	FMP 15244, 38702
Production Date	01.09 2015
Expiration Date	5XP 01.09.2014

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		olourless Juid	Cles colonies
pH (100% 20°C)	JDM001	1.5	2.5	1:6
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

0 1 1 15 50	Name:	Il Ilman Michine
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued electronical		
COA Bi-Spore Base	Version: 01	Date of issuing: September 27th 2012



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 13-Aug-2015 UK32S11442325-1-1

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**

Customer Reference Number:

Account Number:

Product Description:

All in accordance with current Technical Agreement

100432 1002735 Synergy Health Sales Part Reference: P024874 JD-BOTTLES/CAPS/BAGS 25-40kGy 4.1624

Validation Reference: **Quantity Received:** 25.0 **Customer Minimum Specification kGy: Customer Maximum Specification kGy:** 40 O

Customer Unit Lot/Batch Number: B/N W038773 THUR 06 AUG 2015 2 PLTS LOT 1

Order Information

Irradiation Data

Date and Time of Irradiation:	12-Aug-2015 20:05
Reference Dose Range kGy:	32.8 - 33.8
Calculated Minimum Dose kGy:	27.2
Calculated Maximum Dose kGy:	35.3

Items Irradiated under WO38773 will be used in finished product batch number FMP15244 38702



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

Telephone: +44(0)1329 226600 Fax; +44(0)1329 226688

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 **Hightown**

White Cross Industrial Estate

Lancaster LA14XS

Date Received: 10 Sep 2015

Date Tested: 17 Sep 2015

Date Test Completed:

01 Oct 2015

Purchase Order: 25096

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0024637/1

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I; Ph Eur and USP

Date Received:

10/09/2015

Test Article: Sample Code: **Bi-Spore Activator** FMP 15244 38702

Batch Ref: 502304

Qty Received:

20 x 100mL Bottles

Method Item	Result
MM107/00	Pass
MM107/01	No growth in two broths
MM107/02	No growth in two broths
MM107/05 FG047/psd	20 x 50 mL FM04
	MM107/00 MM107/01 MM107/02

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 02 Oct 2015 16:32:07

Mr K.A. Barker

Business Manager - Microbiology

Certificate of Analysis - OSMM Consignment: 0024637 Print Number: P0030025 Page 1 of 1





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Telephone: +44(0)1329 226600 Fax: +44(0)1329 226688

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:

10 Sep 2015

Date Tested:

17 Sep 2015

Date Test Completed:

01 Oct 2015

Purchase Order:

25096

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0024637/2

Test Required:

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Date Received:

10/09/2015

Test Article:

Bi-Spore Base FMP 15244 38702

Sample Code: Batch Ref:

502303

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 and position is shown below.

MB

Date: 02 Oct 2015 16:32:07

Mr K.A. Barker

Business Manager - Microbiology

