

First off



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 15/11/2017

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 17313 43375
Production Date	09/11/2017
Expiration Date	EXP 09/11/2019

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	11.8
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide		100	180	138.375ppm

On behalf of Diversey site Quality Manager	Name :	Parkyisho, Aps Kichma
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7514852	Version : 04	Date of issuing : July 6 th 2012
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CERTIFICATE OF ANALYSIS

Date: 15/11/2017

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 17313 43375
Production Date	09/11/2017
Expiration Date	EXP 09/11/2019

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	1.8
Specific Gravity (20°C)	JDM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Pandy Lish, ap ^l Kineme
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7514852	Version : 04	Date of issuing : July 6 th 2012
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Wickham Laboratories

Contract Analytical Services

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Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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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: 20 Nov 2017
Date Tested: 22 Nov 2017
Date Test Completed: 06 Dec 2017
Purchase Order: 29991

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0039269/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 20/11/2017
Test Article: Bi-Spore Base
Sample Code: FMP17313 43375
Batch Ref: 587518
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

 CBio: MMSE

Date: 07 Dec 2017 16:05:20

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM
Consignment: 0039269
Print Number: P0047541
Page 1 of 1

GMP GLP FDA

Company Registered in England No. 752951



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: 20 Nov 2017
Date Tested: 22 Nov 2017
Date Test Completed: 06 Dec 2017
Purchase Order: 29991

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0039269/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 20/11/2017
Test Article: Bi-Spore Activator
Sample Code: FMP17313 43375
Batch Ref: 583158
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
Tested in Accordance with Ph Eur, USP & JP	MQ005/07	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

 C.Biof. MRSB

Date: 07 Dec 2017 16:05:21

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 21-Sep-2017

UK33S11962706-1-1

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

EN ISO 11137-1:2015 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:	1106825
Customer Reference Number:	P029612
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO43376, 1PLT

Irradiation Data

Date and Time of Irradiation:	21-Sep-2017 11:09
Reference Dose Range kGy:	32.2 - 32.6
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	33.3

Items irradiated under WO43376, will be used in finish product batch FMP17313 43375

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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