



Diversey Europe Operations BV

 Maarssenbroeksedijk 2
 3542 DN Utrecht
 The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 3.02.2017

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	4514852
Batch Number	FMP17031, 41869
Production Date	31.01.2017
Expiration Date	Exp 31/01/2019

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 :	<i>[Signature]</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 27th 2012

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3542 DN Utrecht
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CERTIFICATE OF ANALYSIS

Date: 3.02.2017

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP17031, 41869
Production Date	31.01.2017
Expiration Date	EXP 31/01/2019

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	11.7
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	151.875 ppm

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 Activator	Version : 01	Date of issuing : October 1 st 2012
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Wickham Laboratories

Contract Analytical Services

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
LA1 4XS

Date Received: 07 Feb 2017
Date Tested: 09 Feb 2017
Date Test Completed: 23 Feb 2017
Purchase Order: 28305

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0033700/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/02/2017
Test Article: Bi-Spore Activator
Sample Code: FMP17031 41869
Batch Ref: 552910
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 39 <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.

Date: 24 Feb 2017 10:11:03

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 07 Feb 2017
Date Tested: 09 Feb 2017
Date Test Completed: 23 Feb 2017
Purchase Order: 28305

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0033700/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/02/2017
Test Article: Bi-Spore Base
Sample Code: FMP17031 41869
Batch Ref: 552908
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 39 <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.

Date: 24 Feb 2017 10:11:03

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 09-Jan-2017

UK33S11784166-2-1

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:	P028025
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:	DEV001537, W041870, 1PLT

Irradiation Data

Date and Time of Irradiation:	09-Jan-2017 03:01
Reference Dose Range kGy:	33.1 - 33.9
Calculated Minimum Dose kGy:	27.4
Calculated Maximum Dose kGy:	34.6

Items irradiated under W041870 will be used in finished batch code FMP17031 41869

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