

First off



Diversey Europe Operations BV

Maarssebroeksedijk 2
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The Netherlands

Tel. +31 (0)30 247 8427

CERTIFICATE OF ANALYSIS

Date: 15.06.2017

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FRP 17166 42651
Production Date	15/06/2017
Expiration Date	Exp. 15/06/2019

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	1.6
Specific Gravity (20°C)	JDM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Olga Lavrenko, U. Lavrenko
	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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Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 15.06.17

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 17166 42651
Production Date	15/06/2017
Expiration Date	EXP 15/06/2019

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 (ppm)		100	180	158.63 ppm

On behalf of Diversey site Quality Manager	Name :	<i>H. L. E. J. van der Linde</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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 23-May-2017

UK33S11876727-1-1

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:	P028927
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:	WO42652, 1 PLT

Irradiation Data

Date and Time of Irradiation:	23-May-2017 17:14
Reference Dose Range kGy:	32.7 - 32.7
Calculated Minimum Dose kGy:	27.1
Calculated Maximum Dose kGy:	33.4

Items irradiated under WO42652, are to be used in finished product batch FMP17166 42651

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



Wickham Laboratories

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Ms D Henderson
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Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 22 Jun 2017
Date Tested: 27 Jun 2017
Date Test Completed: 11 Jul 2017
Purchase Order: 29114

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0036303/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/06/2017
Test Article: Bi-Spore Base
Sample Code: FMP17166 42651
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 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.

 CMO MRSB

Date: 12 Jul 2017 09:15:28

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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Date Received: 22 Jun 2017
Date Tested: 27 Jun 2017
Date Test Completed: 11 Jul 2017
Purchase Order: 29114

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0036303/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/06/2017
Test Article: Bi-Spore Activator
Sample Code: FMP17166 42651
Batch Ref: 570743
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.

 CB: Mrs C Moore

Date: 12 Jul 2017 09:15:28

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology