

First off



Diversey Europe Operations BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427
www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 29/06/2018

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 18178 45757
Production Date	27/06/2018
Expiration Date	EXP 27/06/2020

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 (neat solution)	DM001	1.5	2.5	1.5
Specific Gravity (20°C)	DM004	1.010	1.030	1.016

On behalf of Diversey site Quality Manager	Name :	Bartje de Vries, Van der Velden
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24 th 2017
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CERTIFICATE OF ANALYSIS

Date: 29/06/2018

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP18178 45757
Production Date	27/06/2018
Expiration Date	EXP 27/06/2020

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 (neat solution)	DM001	9.0	12.5	11.7
Specific Gravity (20°C)	DM004	1.004	1.020	1.008
Potential Chlorine Dioxide (ppm)		100	180	151.875

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

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Wickham Laboratories

Contract Analytical Services

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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: 05 Jul 2018
Date Tested: 10 Jul 2018
Date Test Completed: 24 Jul 2018
Purchase Order: 31329

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0043549/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 05/07/2018
Test Article: BI-Spore Base
Sample Code: FMP18178 45757
Batch Ref: 610100
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 41 <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: 25 Jul 2018 10:51:39

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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


Date Received: 05 Jul 2018
Date Tested: 10 Jul 2018
Date Test Completed: 24 Jul 2018
Purchase Order: 31329

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0043549/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 05/07/2018
Test Article: BI-Spore Activator
Sample Code: FMP18178 45757
Batch Ref: 610101
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 41 <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 Moore, MMSB

Date: 25 Jul 2018 10:51:39

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 21-May-2018

UK33S12104781-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	P031016
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	16
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO45392, 2 PLTS

Irradiation Data

Date and Time of Irradiation:	18-May-2018 08:30
Reference Dose Range kGy:	31.7 - 33.4
Calculated Minimum Dose kGy:	26.3
Calculated Maximum Dose kGy:	34.1

Items irradiated under WO45392, will be used in finished product batch FMP18178 45757.

C Pascoe

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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