

Base First off



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 12.08.17

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	F4P 17223 43362
Production Date	11/08/2017
Expiration Date	Exp. 11/08/2019

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 :	Debra Kinnear, Bartyin sb
	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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Activator First off



Diversey Europe Operations BV

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3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 11.08.2017

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP 17223 43362
Production Date	11/08/2017
Expiration Date	Exp. 11/08/2019

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	12.0
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008
Potential Chlorine Dioxide		100	180	165.375ppm

On behalf of Diversey site Quality Manager	Name :	Olga Kienner, Butyuska
	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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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 09-Aug-2017

UK33S11933911-3-1

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:	P029335
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:	WO43361, 1 PLT

Irradiation Data

Date and Time of Irradiation:	09-Aug-2017 08:53
Reference Dose Range kGy:	33.4 - 34.3
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	35.0

Items irradiated under WO43361, will be used in finished product batch FMP17223 43362

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



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

Date Received: 16 Aug 2017
Date Tested: 22 Aug 2017
Date Test Completed: 05 Sep 2017
Purchase Order: 29436

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037404/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 16/08/2017
Test Article: Bi-Spore (Base)
Sample Code: FMP17223 43362
Batch Ref: 570742
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

Comments

Corrected Certificate of Analysis to LR:0037404/2 authorised 07 September 17 due to incorrect number of tests referenced.

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

BSc, CBiol, MRSB

Date: 26 Sep 2017 09:54:03

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 16 Aug 2017
Date Tested: 22 Aug 2017
Date Test Completed: 05 Sep 2017
Purchase Order: 29436

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037404/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 16/08/2017
Test Article: Bi-Spore (Activator)
Sample Code: FMP17223 43362
Batch Ref: 570880
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

Comments

Corrected Certificate of Analysis to LR:0037404/1 authorised 07 September 17 due to incorrect number of tests referenced.

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

BSc. CBiol. MRSB

Date: 26 Sep 2017 09:54:03

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology