synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 12-Aug-2016 **UK33S11670115-2-2**

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:	P026987
Product Description:	BI-SP B3 COMPONENTS 25-40kGy TRIPLE VAL
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	TRIPLE VALIDATION, DEV001537, WO41032, 2 plts
Other Process Details:	Actual min dose: 27.2kGy Actual max dose: 39.1kGy

Irradiation Data

Date and Time of Irradiation:	12-Aug-2016 08:30

Items Irradiated under Wo41032 will be used in finished batch code FMP16286 41033

Irradiation Release Authorised By Synergy Health plc

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Certificate of Irradiation

Date Issued: 12-Oct-2016 **UK33S11708302-2-1**

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

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UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1106825
Customer Reference Number:	P027330
Product Description:	BI-SP B3 COMPONENTS DV4725 25-40kGy
Validation Reference:	4725
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	WO41032, 1 PLT

Irradiation Data

Date and Time of Irradiation:	11-Oct-2016 19:07
Reference Dose Range kGy:	33.9 - 33.9
Calculated Minimum Dose kGy:	28.1
Calculated Maximum Dose kGy:	34.6

Items Irradiated under WO41032 will be used in finished batch code FMP16286 41033

Irradiation Release Authorised By Synergy Health plc

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Ms D Henderson
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 19 Oct 2016
Date Tested: 24 Oct 2016
Date Test Completed: 07 Nov 2016
Purchase Order: 27516

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0031743/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 19/10/2016
Test Article: Bi-Spore
Sample Code: FMP16286 41033
Batch Ref: Base
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 8.0 2.6.1, USP 39 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM05

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

Date: 08 Nov 2016 09:49:29

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

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Ms D Henderson
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Date Received: 19 Oct 2016
Date Tested: 24 Oct 2016
Date Test Completed: 07 Nov 2016
Purchase Order: 27516

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0031743/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 19/10/2016
Test Article: Bi-Spore
Sample Code: FMP16286 41033
Batch Ref: Acitvator
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 8.0 2.6.1, USP 39 <71> & JP XVI 4.06
Product Standard Data Sheet	FG047/psd	FM04

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

Date: 08 Nov 2016 09:49:29

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

FIRST OFF

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 12.10.16

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FHP 16286 41033
Production Date	12/10/2016
Expiration Date	EXP 12/10/2019.

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 Lower - Upper		Results
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (100% 20°C)	JDM001	9.0	12.5	12.3.
Specific Gravity (20°C)	JDM004	1.004	1.020	1.008.
Potential Chlorine Dioxide (ppm)		100	180	158.625

On behalf of Diversey site Quality Manager	Name :	Partyka, Kinchne
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator	*Version : 01*	*Date of issuing : October 1st 2012*

FIRST OFF

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 13.10.16

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP16286 41033
Production Date	12/10/2016
Expiration Date	EXP 12/10/2018

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 Lower	Limits Upper	Results
Appearance	Visual	Clear Colourless Liquid		Clear Colourless Liquid
pH (100% 20°C)	JDM001	1.5	2.5	1.7
Specific Gravity (20°C)	JDM004	1.010	1.030	1.020

On behalf of Diversey site Quality Manager	Name :	Partyisko, Kinchma.
	Position	Quality Control Inspector

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