Base First off

Diversey Europe Operations BV

Maarssenbroeksedijk 2
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The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 16.08.2017

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP17 228 42857
Production Date	16/08/2017
Expiration Date	EXP 16/08/2019

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 Lower - 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 :	Olga Kanchner, Pawlyshyn
	Position	Quality Control Inspector

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Activator Fivst off

Diversey Europe Operations BV

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3542 DN Utrecht
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CERTIFICATE OF ANALYSIS

Date: 16.08.2017

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514852
Batch Number	FMP17228 42857
Production Date	16/08/2017
Expiration Date	EXP 16/08/2019

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 Lower - Upper		Results
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		100	180	155.25 ppm

On behalf of Diversey site Quality Manager	Name :	Olga Lavenne, Partyish
	Position	Quality Control Inspector

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synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 14-Aug-2017 **UK33S11902568-2-1**

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:	P029110
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:	WO42858, 1 PLT
Other Process Details:	This batch has received an underdose Reference s11913298-1-1 has delivered a top up dose of 2.6-3.2kGy. Total certifiable minimum dose - 27.4kGy Total certifiable maximum dose - 35.6kGy

Irradiation Data

Date and Time of Irradiation:	26-Jun-2017 21:40
Reference Dose Range kGy:	29.9 - 31.8
Calculated Minimum Dose kGy:	24.8
Calculated Maximum Dose kGy:	32.4

Items irradiated under WO42858, will be used in finished product batch FMP17228 42857

Irradiation Release Authorised By Synergy Health plc

Wickham Laboratories Ltd
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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 22 Aug 2017
Date Tested: 31 Aug 2017
Date Test Completed: 14 Sep 2017
Purchase Order: 29454

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037518/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/08/2017
Test Article: Bi-Spore (Activor)
Sample Code: FMP17228 42857
Batch Ref: 578511
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

See deviation report PHM 2017 219.

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

CBiol MRSB Date: 15 Sep 2017 16:23:13

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 22 Aug 2017
Date Tested: 31 Aug 2017
Date Test Completed: 14 Sep 2017
Purchase Order: 29454

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0037518/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/08/2017
Test Article: Bi-Spore (Base)
Sample Code: FMP17228 42857
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

See deviation report PHM 2017 219.

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

CBioS MMSB Date: 15 Sep 2017 16:23:13

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA