Base first off

Diversey

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 26/6/14

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP14175 36421
Production Date	06/2014
Expiration Date	06/2015

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	1.9
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	C Mascoe, Olga Sinchm
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 24/6/14

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP14175 36421
Production Date	06/2014
Expiration Date	06/2015

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	12.1
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	168.75ppm

On behalf of Diversey site Quality Manager	Name :	[signature], Ana Kirchner
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 22-Jun-2014 **UK32S11177509-1-1**

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 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:	1002735
Customer Reference Number:	P022341
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.1624
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	B/NO.W036420 THUR 05.06.14 2 PLTS LOT NO.3

Irradiation Data

Date and Time of Irradiation:	22-Jun-2014 10:52
Reference Dose Range kGy:	34.8 - 34.9
Calculated Minimum Dose kGy:	28.9
Calculated Maximum Dose kGy:	36.5

Items irradiated under WO36420 will be used in finished product batch code FMP14175 36421 K Gallagher 03.07.2014

Irradiation Release Authorised By Synergy Health plc

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: 04 Jul 2014
Date Tested: 09 Jul 2014
Date Test Completed: 23 Jul 2014
Purchase Order: PO22531

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017475/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 04/07/2014
Test Article: Bi Spore Base
Sample Code: -
Batch Ref: FMP14175 36421
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
Product Standard Data Sheet	FG047/psd	FM05

Comments

Test carried out according to current Pharmacopoeias.

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

CMoore Date: 24 Jul 2014 14:38:08

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Wickham Laboratories
Contract Analytical Services

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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 04 Jul 2014
Date Tested: 09 Jul 2014
Date Test Completed: 23 Jul 2014
Purchase Order: PO22531

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017475/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 04/07/2014
Test Article: Bi Spore Activator
Sample Code: -
Batch Ref: FMP14175 36421
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
Product Standard Data Sheet	FG047/psd	FM04

Comments
Test carried out according to current Pharmacopoeias.

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

CMoore Date: 24 Jul 2014 14:38:08

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology