FIRST OFF

Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 31.10.2015

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7515828
Batch Number	FMP 15300 38776
Production Date	27/10/2015
Expiration Date	EXP 27/10/2017

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	1.018

On behalf of Diversey site Quality Manager	Name :	M. Ulrich Partyka
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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CERTIFICATE OF ANALYSIS

Date: 31.10.2015

Product Name	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7515828
Batch Number	FMP 15300 38776
Production Date	27/10/2015
Expiration Date	EXP 27/10/2017

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	9.0	12.5	11.9
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	172.125

On behalf of Diversey site Quality Manager	Name :	Ulrike Pawlyszyn
	Position	Quality Control Inspector

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synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 07-Aug-2015 **UK32S11437538-1-1**

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:	P024827
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/N WO38701 THUR 30 JUL 2015 2 PLTS LOT 1

Irradiation Data

Date and Time of Irradiation:	07-Aug-2015 10:15
Reference Dose Range kGy:	34.2 - 35.0
Calculated Minimum Dose kGy:	28.4
Calculated Maximum Dose kGy:	36.6

Items Irradiated under WO38701 will be used in finished product batch number FMP15300 38776

E Gaughn 02.11.15

Irradiation Release Authorised By Synergy Health plc

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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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: 03 Nov 2015
Date Tested: 10 Nov 2015
Date Test Completed: 24 Nov 2015
Purchase Order: 25426

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025624/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 03/11/2015
Test Article: Clearklens Bi Spore Activator
Sample Code: FMP 15300 38776
Batch Ref: 515685
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.

Date: 25 Nov 2015 13:16:09

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

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: 03 Nov 2015
Date Tested: 10 Nov 2015
Date Test Completed: 24 Nov 2015
Purchase Order: 25426

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0025624/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 03/11/2015
Test Article: Clearklens Bi Spore Base
Sample Code: FMP 15300 38776
Batch Ref: 513475
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.

Date: 25 Nov 2015 13:16:10

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology