



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 7.07.14

Product Name	CLEARLENSE BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7514 852
Batch Number	FMP 14188 36566
Production Date	07/2014
Expiration Date	07/2015

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		Results
		Lower	Upper	
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	1.006
Potential Chlorine Dioxide (ppm)		100	180	162 ppm

On behalf of Diversey site Quality Manager	Name :	Alpa Kinnara, C. Pascoe
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Activator	Version : 01	Date of issuing : October 1 st 2012
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CERTIFICATE OF ANALYSIS

Date: 7.07.14

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7514852
Batch Number	FMP 14188 36566
Production Date	07/2014
Expiration Date	07/2015.

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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		clear colourless liquid
pH (100% 20°C)	JDM001	1.5	2.5	2.1
Specific Gravity (20°C)	JDM004	1.010	1.030	1.018

On behalf of Diversey site Quality Manager	Name :	Olga Kuchner
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Bi-Spore Base	Version : 01	Date of issuing : September 27 th 2012
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 25-Jun-2014

UK32S11185028-1-1

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:	P022418
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.WO36565 THUR 19.06.14 2 PLTS LOT NO.2

Irradiation Data

Date and Time of Irradiation:	25-Jun-2014 05:29
Reference Dose Range kGy:	33.7 - 34.3
Calculated Minimum Dose kGy:	27.9
Calculated Maximum Dose kGy:	35.9

Items irradiated under WO36565 will be used in finished product batch code FMP14188 36566

E. Clayton 11.07.2014

Irradiation Release Authorised By Synergy Health plc

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



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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: 14 Jul 2014
Date Tested: 16 Jul 2014
Date Test Completed: 30 Jul 2014
Purchase Order: 22573

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017626/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 14/07/2014
Test Article: Bi Spore Activator
Sample Code: -
Batch Ref: FMP14188 36566
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: 31 Jul 2014 16:56:41

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0017626

Certificate of Analysis - OSMM

Print Number: P0021662

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ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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: 14 Jul 2014
Date Tested: 16 Jul 2014
Date Test Completed: 30 Jul 2014
Purchase Order: 22573

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017626/2
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 14/07/2014
Test Article: Bi Spore Base
Sample Code: -
Batch Ref: FMP14188 36566
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: 31 Jul 2014 16:56:41

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0017626

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