

Hydrovator FIRST OFF  
Base first off



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 26/2/14

Product Name	CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26
Product Code	7518162
Batch Number	FMPI4057 35732
Production Date	02/2014
Expiration Date	02/2015

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	11.6
Specific Gravity (20°C)	JDM004	1.004	1.020	1.006
Potential Chlorine Dioxide (ppm)		100	180	155.25ppm

On behalf of Diversey site Quality Manager	Name :	<i>C. P. P. J. D. K. K. K.</i>
	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 <sup>st</sup> 2012
------------------------	--------------	--

REVISION 111 J 111  
Base First off



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 28.02.14

Product Name	CLEARKLENS BI-SPORE BASE SOLUTION VH26
Product Code	7518162
Batch Number	FMP14057 35732
Production Date	02/2014
Expiration Date	02/2015

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	1.9
Specific Gravity (20°C)	JDM004	1.010	1.030	1.014

On behalf of Diversey site Quality Manager	Name :	O. Kirchner, Amateure
	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 <sup>th</sup> 2012
-------------------	--------------	---



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 12-Feb-2014

UK32S11106040-1-1

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:	P021684
Product Description:	JD-BOTTLES/CAPS/BAGS 25-40kGy
Validation Reference:	4.0500
Quantity Received:	8
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	40.0
Customer Unit Lot/Batch Number:	LOT 2; 2 PLTS; THUR 30.01.14; B/NO. W035729
Other Process Details:	Released against validation 4.1624, Minimum calculated dose 28.8 kGy, Maximum calculated dose 38.2 kGy.

## Irradiation Data

Date and Time of Irradiation:	08-Feb-2014 21:59
-------------------------------	-------------------

Items irradiated under W035729 will be used in finished product batch code FMP14057 35732

*E. Gough* 07.03.2014

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:** 06 Mar 2014  
**Date Tested:** 11 Mar 2014  
**Date Test Completed:** 25 Mar 2014  
**Purchase Order:** PO21884

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0015331/2  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 06/03/2014  
**Test Article:** Bi Spore Base  
**Sample Code:** FMP14057 35732  
**Batch Ref:** 446480  
**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: 26 Mar 2014 15:36:47

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015331

Certificate of Analysis - OSMM

Print Number: P0018589

Page 1 of 1

ISO  
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,  
Registered Office: Winchester Road, Wickham, Fareham, 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:** 06 Mar 2014  
**Date Tested:** 11 Mar 2014  
**Date Test Completed:** 25 Mar 2014  
**Purchase Order:** PO21884

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0015331/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 06/03/2014  
**Test Article:** Bi Spore Activator  
**Sample Code:** FMP14057 35732  
**Batch Ref:** 453739  
**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: 26 Mar 2014 15:36:47

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015331

Certificate of Analysis - OSMM

Print Number: P0018589

Page 1 of 1

ISO  
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,  
Registered Office: Winchester Road, Wickham, Fareham, Hampshire