

Activator First off (filter)



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 25.02.2013

<b>Product Name</b>	CLEARKLENS BI-SPORE ACTIVATOR SOLUTION VH26
<b>Product Code</b>	7514852
<b>Batch Number</b>	FMP13054 33521
<b>Production Date</b>	02 / 2013
<b>Expiration Date</b>	02 / 2014

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	11.8
Specific Gravity (20°C)	JDM004	1.004	1.020	1.005
Potential Chlorine Dioxide (ppm)		100	180	135 ppm

On behalf of Diversey site Quality Manager	Name :	A. Maturo
	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
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Base First off (filter)



Diversey Europe Operations BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 25.02.2013

<b>Product Name</b>	CLEARLENs BI-SPORE BASE SOLUTION VH26
<b>Product Code</b>	7514852
<b>Batch Number</b>	FNP 13054 33521
<b>Production Date</b>	02/2013
<b>Expiration Date</b>	02/2014

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	1.013

On behalf of Diversey site Quality Manager	Name :	A. Makina, c/pascoe
	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
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<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 18-Feb-2013

UK32S11007164-1-1

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

ISO 11137:2006 Sterilisation of Health Care Products

ISO 9001:2008 Quality Management System

ISO 13485:2003 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

Customer Reference Number:	PO19917
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 FMP13054-33521 (E9) 26-02-13.
Customer Unit Lot/Batch Number:	B/No.33515 , 2 PLTS LOT 2 THURS 14.2.13
Shop Order Number:	S11007164-1-1
Synergy Health Sales Part Reference:	1002735

### Irradiation Data

Date and Time of Irradiation:	18-Feb-2013 16:18
Reference Dose Range kGy:	35.1 - 35.7
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	37.0

Comments:

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 Limited,  
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Mr J Jackson  
Flexible Medical Packaging Limited  
Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 27 Feb 2013  
**Date Tested:** 03 Mar 2013  
**Date Test Completed:** 17 Mar 2013  
**Purchase Order:** 19995

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0009072/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 27/02/2013  
**Test Article:** Bi-Spore Activator  
**Sample Code:** 420897  
**Batch Ref:** FMP13054 33521  
**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 is shown below.

*Suz Wood*

Date: 20 Mar 2013 09:30:13

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0009072

Certificate of Analysis - OSMM

Print Number: P0009269

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# Wickham Laboratories

contract analytical services

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Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

**Date Received:** 27 Feb 2013  
**Date Tested:** 03 Mar 2013  
**Date Test Completed:** 17 Mar 2013  
**Purchase Order:** 19995

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0009072/2  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 27/02/2013  
**Test Article:** Bi-Spore Base  
**Sample Code:** 420896  
**Batch Ref:** FMP13054 33521  
**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 is shown below.

*Sarah Wood*

Date: 20 Mar 2013 09:30:13

Mrs S.L. Wood, BSc (Hons), CBiol, MSB  
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0009072

Certificate of Analysis - OSMM

Print Number: P0009269

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