

First off.



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 9.03.2017

| | |
|-----------------|--|
| Product Name | CLEARKLENS BI-SPORE BASE SOLUTION VH26 |
| Product Code | 7515828 |
| Batch Number | FLP 17066 42045 |
| Production Date | 07/03/2017 |
| Expiration Date | Exp. 07/03/2019 |

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 | 1.6 |
| Specific Gravity (20°C) | JDM004 | 1.010 | 1.030 | 1.016 |
| | | | | |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

COA Bi-Spore Base

Version : 01

Date of issuing : September 27th 2012

First off



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3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 9.03.2017

| | |
|-----------------|--|
| Product Name | CLEARLENs BI-SPORE ACTIVATOR SOLUTION VH26 |
| Product Code | 7515828 |
| Batch Number | RMP 17066 42045 |
| Production Date | 07/03/2017 |
| Expiration Date | Exp. 07/03/2019 |

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 | 11.9 |
| Specific Gravity (20°C) | JDM004 | 1.004 | 1.020 | 1.008 |
| Potential Chlorine Dioxide (ppm) | | 100 | 180 | 168.75 ppm |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | Alpa Lincine, H. Hine |
| | 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 |
|------------------------|--------------|--|



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
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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: 15 Mar 2017
Date Tested: 22 Mar 2017
Date Test Completed: 05 Apr 2017
Purchase Order: 28553

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034456/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 15/03/2017
Test Article: Bi-Spore (Activator)
Sample Code: FMP17066 42045
Batch Ref: 553611
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 |

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

Date: 06 Apr 2017 13:04:18

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 15 Mar 2017
Date Tested: 22 Mar 2017
Date Test Completed: 05 Apr 2017
Purchase Order: 28553

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034456/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 15/03/2017
Test Article: Bi-Spore (Base)
Sample Code: FMP17066 42045
Batch Ref: 552908
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 |

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

Date: 06 Apr 2017 13:04:18

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 12-Feb-2017

UK33S11808300-2-1

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

EN ISO 11137-1:2015 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: | 1106825 |
| Customer Reference Number: | P028309 |
| Product Description: | BI-SP B3 COMPONENTS DV4725 25-40kGy |
| Validation Reference: | 4725 |
| Quantity Received: | 8 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 40.0 |
| Customer Unit Lot/Batch Number: | WO42047, 1 plt |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 12-Feb-2017 13:16 |
| Reference Dose Range kGy: | 32.9 - 33.0 |
| Calculated Minimum Dose kGy: | 27.2 |
| Calculated Maximum Dose kGy: | 33.7 |

Items irradiated under WO42047 are to be used in finished product batch FMP17066 42045

10/04/17
 CAPTAIN

Irradiation Release Authorised By Synergy Health plc

Processing Site: Brunel Close, Drayton Fields Industrial Estate, Daventry, NN11 8RB Phone No: +44 (0) 1327 706111

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