



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 27.10.14

|                 |                   |
|-----------------|-------------------|
| Product Name    | CLEARLENs IPA VH1 |
| Product Code    | 7513400           |
| Batch Number    | FMP 14282 36926   |
| Production Date | 10/2014           |
| Expiration Date | 10/2016           |

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 |
| Specific Gravity (20°C) | JDM004      | 0.872                   | 0.883 | 0.875                   |
|                         |             |                         |       |                         |
|                         |             |                         |       |                         |

|   |          |                           |
|---|----------|---------------------------|
| On behalf of Diversey site<br>Quality Manager | Name :   | Alpa Kichna, Madhus       |
|   | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

|             |              |  |
|-------------|--------------|--|
| COA 7513400 | Version : 03 | Date of issuing : November 28 <sup>th</sup> 2011 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 17-Oct-2014

UK32S11258848-1-1

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

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## Order Information

|                                      |   |
|--------------------------------------|---|
| Account Number:                      | 100432  |
| Synergy Health Sales Part Reference: | 1002734   |
| Customer Reference Number:           | PO23124   |
| Product Description:                 | JD IPA BOTTLES 25-45kGy   |
| Validation Reference:                | 4.1723  |
| Quantity Received:                   | 532   |
| Customer Minimum Specification kGy:  | 25.0  |
| Customer Maximum Specification kGy:  | 45.0  |
| Customer Unit Lot/Batch Number:      | 527 X B/N FMP14282 36926 + 5 SAMPLES THUR<br>16.10.14 10 PLTS LOT 1 |

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## Irradiation Data

|                               |                   |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 17-Oct-2014 19:25 |
| Reference Dose Range kGy:     | 37.0 - 38.4       |
| Calculated Minimum Dose kGy:  | 26.1              |
| Calculated Maximum Dose kGy:  | 41.0              |

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Irradiation Release Authorised By Synergy Health plc

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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:** 27 Oct 2014  
**Date Tested:** 30 Oct 2014  
**Date Test Completed:** 13 Nov 2014  
**Purchase Order:** PO23189

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0019417/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 27/10/2014  
**Test Article:** CLEARKLENS IPA BLOCK 1  
**Sample Code:** 5939  
**Batch Ref:** FMP 14282 36926  
**Qty Received:** 20 x 900mL Bottle + 1 spare

| 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 one broth |
| Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days | MM107/02    | No growth in one broth |
| Volume Tested  | MM107/05    | 20 x 50 mL             |
| Product Standard Data Sheet                                    | FG047/psd   | FM03                   |

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 14 Nov 2014 15:45:53

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0019417

Certificate of Analysis - OSMM

Print Number: P0023816

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





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LA1 4XS

**Date Received:** 27 Oct 2014  
**Date Tested:** 30 Oct 2014  
**Date Test Completed:** 13 Nov 2014  
**Purchase Order:** PO23189

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0019417/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 27/10/2014  
**Test Article:** CLEARKLENS IPA BLOCK 1  
**Sample Code:** 5939  
**Batch Ref:** FMP 14282 36926  
**Qty Received:** 20 x 900mL Bottle + 1 spare

| 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 one broth |
| Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days | MM107/02    | No growth in one broth |
| Volume Tested  | MM107/05    | 20 x 50 mL             |
| Product Standard Data Sheet                                    | FG047/psd   | FM03                   |

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Ms D Henderson  
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Lancaster  
LA1 4XS

**Date Received:** 27 Oct 2014  
**Date Tested:** 28 Oct 2014  
**Date Test Completed:** 28 Oct 2014  
**Purchase Order:** PO23189

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0019417/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 27/10/2014  
**Test Article:** CLEARLENs IPA BLOCK 1  
**Sample Code:** 5939  
**Batch Ref:** FMP 14282 36926  
**Qty Received:** 1 x 900mL Bottle

| Test                                    | Method Item | Result     |
|---|-------------|------------|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00    | <0.2 EU/mL |
| Spiked Recovery                         | MM110/01    | 65 %       |
| Dilution Tested                         | MM110/04    | 1/40       |
| Endotoxin Spike Level                   | MM110/02    | 0.5 EU/mL  |
| Product Standard Data Sheet             | FG047/psd   | FM02       |

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 29 Oct 2014 14:58:47

Mr K.A. Barker  
Business Manager - Microbiology

Consignment: 0019417

Certificate of Analysis - OSMM

Print Number: P0023485

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