

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 11/6/13

| Product Name | CLEARKLENS IPA VH1 | |
|------------------------|--------------------|---|
| Product Code | 7514372 | · |
| Batch Number | FMP13135 3404Z | |
| Production Date | 05/2013 | |
| Expiration Date | 05/2015 | |

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 Co | olourless | Cler COLOUTH |
| | | Lic | uid | 11901d |
| Specific Gravity (20°C) | JDM004 | 0.872 | 0.883 | 0.877 |
| | | | | |
| | | | , | |

| O habalfaf Diamania | Name: | Chara A. Hadana |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Position | Quality Control Inspector |

| This | document | being | issued | electronically | y does n | ot bear a | signature | |
|------|----------|-------|--------|----------------|----------|-----------|-----------|--|
|------|----------|-------|--------|----------------|----------|-----------|-----------|--|

| COA 7514372 | Version: 03 | Date of issuing: November 28th 2011 |
|-------------|-------------|-------------------------------------|



http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 05-Jun-2013

UK32S11023269-1-1

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 13485:2012 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 | | | |
|--------------------------------------|--|--|--|
| Customer Reference Number: | P020493 | | |
| Product Description: | JD DE 900ML BOTTLES 25-45kGy | | |
| Validation Reference: | 4.0624 | | |
| Quantity Received: | 210 | | |
| Customer Minimum Specification kGy: | 25.0 | | |
| Customer Maximum Specification kGy: | 45.0 | | |
| Customer Unit Lot/Batch Number: | 205 X B/No. FMP13135/34042 , P/REF, 7514372 + 5 SAMPLES , 4 PLTS LOT 3 THURS 23.5.13 | | |
| Shop Order Number: | S11023269-1-1 | | |
| Synergy Health Sales Part Reference: | 1002733 | | |
| Ir | radiation Data | | |
| Date and Time of Irradiation: | 05-Jun-2013 04:03 | | |
| Reference Dose Range kGy: | 35.6 - 36.8 | | |
| Calculated Minimum Dose kGy: | 25.4 | | |
| Calculated Maximum Dose kGy: | 38.9 | | |



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Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS **Date Received:**

10 Jun 2013

Date Tested:

13 Jun 2013

Date Test Completed:

27 Jun 2013

Purchase Order:

20524

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0010702/1

Test Required:

Sterility Test by Membrane Filtration (Steritest)

Date Received:

10/06/2013

Clearklens IPA Block

Test Article: Sample Code:

4426

Batch Ref:

FMP13135 34042

Qty Received:

20 x 900mL (and 3 spare 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 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 |
| Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days Volume Tested | MM107/05 | 20 x 50 mL |

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

Ens Lous.

Date: 01 Jul 2013 08:49:16

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0010702

Certificate of Analysis - OSMM

Print Number: P0011622

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Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster

LA14XS

Date Received:

10 Jun 2013

Date Tested:

14 Jun 2013

Date Test Completed:

14 Jun 2013

Purchase Order:

20524

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0010702/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Date Received: 10/06/2013

Test Article:

Clearklens IPA Block

Sample Code:

4426

Batch Ref: Qty Received: FMP13135 34042 1 x 900mL Bottle

| Test | Method Item | Result |
|--|-------------|------------|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00 | <0.2 EU/mL |
| Spiked Recovery | MM110/01 | 101 % |
| 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 is shown below.

Ever Used

Date: 14 Jun 2013 16:48:39

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0010702

Certificate of Analysis - OSMM

Print Number: P0011255

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