



Diversey Europe BV
 Maarssebroeksedijk 2
 3542 DN Utrecht
 The Netherlands
 Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 18/6/13

| | |
|-----------------|--------------------|
| Product Name | CLEARKLENS IPA VH1 |
| Product Code | 7514372 |
| Batch Number | IMP13143 34048 |
| 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 Colourless Liquid | | clear colourless liquid |
| Specific Gravity (20°C) | JDM004 | 0.872 | 0.883 | 0.877 |
| | | | | |
| | | | | |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | <i>Alfred O. Kienner</i> |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 17-Jun-2013

UK32S11026738-1-1

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: | PO20515 |
| Product Description: | JD IPA BOTTLES 25-45kGy |
| Validation Reference: | 4.0621 |
| Quantity Received: | 712 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 707 X B/No.FMP13143/34048 + 5 SAMPLES , 14 PLTS LOT 2 THURS 6.6.13 |
| Shop Order Number: | S11026738-1-1 |
| Synergy Health Sales Part Reference: | 1002734 |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 15-Jun-2013 19:42 |
| Reference Dose Range kGy: | 37.5 - 39.0 |
| Calculated Minimum Dose kGy: | 27.1 |
| Calculated Maximum Dose kGy: | 41.4 |

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



Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 19 Jun 2013
Date Tested: 20 Jun 2013
Date Test Completed: 20 Jun 2013
Purchase Order: 20587

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0010885/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 19/06/2013
Test Article: Clearklens IPA Block 2
Sample Code: -
Batch Ref: FMP13143 34048
Qty Received: 1x 900mL bottle

| Test | Method Item | Result |
|---|-------------|------------|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00 | <0.2 EU/mL |
| Spiked Recovery | MM110/01 | 104 % |
| 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.

Suz Wood

Date: 21 Jun 2013 16:33:34

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



Wickham Laboratories

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 19 Jun 2013
Date Tested: 28 Jun 2013
Date Test Completed: 12 Jul 2013
Purchase Order: 20587

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0010885/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 19/06/2013
Test Article: Clearklens IPA Block 2
Sample Code: -
Batch Ref: FMP13143 34048
Qty Received: 20 x 900mL bottles + 2 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 is shown below.

Suz Wood

Date: 16 Jul 2013 13:41:36

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

Consignment: 0010885

Certificate of Analysis - OSMM

Print Number: P0011950

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