



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 20.03.2014

| | |
|-----------------|-------------------|
| Product Name | CLEARLENs IPA VH1 |
| Product Code | 7513400 |
| Batch Number | FMP 14057 35728 |
| Production Date | 02 / 2014 |
| Expiration Date | 02 / 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 Quality Manager | Name : | Maureen Partykalis |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|--|
| COA 7513400 | Version : 03 | Date of issuing : November 28 th 2011 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 17-Mar-2014

UK32S11123758-1-1

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

Order Information

| | |
|--------------------------------------|---|
| Account Number: | 100432 |
| Synergy Health Sales Part Reference: | 1002734 |
| Customer Reference Number: | P021885 |
| Product Description: | JD IPA BOTTLES 25-45kGy |
| Validation Reference: | 4.0621 |
| Quantity Received: | 706 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 13 PLTS; THUR 06.03.14; 701 x B/NO. FMP14057 35728 + 5 SAMPLES |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 15-Mar-2014 05:54 |
| Reference Dose Range kGy: | 37.0 - 37.2 |
| Calculated Minimum Dose kGy: | 26.7 |
| Calculated Maximum Dose kGy: | 39.5 |

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

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

Date Received: 20 Mar 2014
Date Tested: 21 Mar 2014
Date Test Completed: 21 Mar 2014
Purchase Order: 21946

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0015632/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 20/03/2014
Test Article: ClearKlens IPA Block 1
Sample Code: 5293
Batch Ref: FMP14057 35728
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 | 108 % |
| 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: 25 Mar 2014 17:30:06

Mrs S.L. Wood
Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015632

Certificate of Analysis - OSMM

Print Number: P0018558

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Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Winchester Road, Wickham, Fareham, Hampshire



Wickham Laboratories

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Date Received: 20 Mar 2014
Date Tested: 28 Mar 2014
Date Test Completed: 11 Apr 2014
Purchase Order: 21946

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0015632/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 20/03/2014
Test Article: ClearKlens IPA Block 1
Sample Code: 5293
Batch Ref: FMP14057 35728
Qty Received: 20 x 900mL 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 |

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 14 Apr 2014 13:09:19

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0015632

Certificate of Analysis - OSMM

Print Number: P0019178

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