



Diversey Europe BV

Maarssebroeksewijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 13/5/17

| | |
|-----------------|-------------------|
| Product Name | CLEARLENS IPA VH1 |
| Product Code | 7513400 |
| Batch Number | FMP 17115 42464 |
| Production Date | 25/04/2017 |
| Expiration Date | EXP 25/04/2019 |

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 |
| Specific Gravity (20°C) | JDM004 | 0.872 | 0.883 | 0.876 |
| | | | | |
| | | | | |

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

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|--|
| COA 7513400 | Version : 03 | Date of issuing : November 28 th 2017 |
|-------------|--------------|--|

Certificate of Irradiation

Date Issued: 12-May-2017

UK33S11871653-1-1

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: | 1104747 |
| Customer Reference Number: | P028880 |
| Product Description: | IPA BOTTLE DV4648 25-45kGy |
| Validation Reference: | 4648 |
| Quantity Received: | 867 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | FMP17115 42464, 16 plts |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 12-May-2017 02:32 |
| Reference Dose Range kGy: | 34.8 - 35.2 |
| Calculated Minimum Dose kGy: | 27.5 |
| Calculated Maximum Dose kGy: | 39.8 |

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 05-May-2017

UK33S11867319-3-1

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

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All in accordance with current Technical Agreement

Order Information

| | |
|--------------------------------------|---|
| Account Number: | 100432 |
| Synergy Health Sales Part Reference: | 1104747 |
| Customer Reference Number: | P028853 |
| Product Description: | IPA BOTTLE DV4648 25-45kGy |
| Validation Reference: | 4648 |
| Quantity Received: | 544 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | FMP17115, 42464, INC 4 SAMPLES, 10 PLTS |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 05-May-2017 02:35 |
| Reference Dose Range kGy: | 35.8 - 36.0 |
| Calculated Minimum Dose kGy: | 28.3 |
| Calculated Maximum Dose kGy: | 40.7 |

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



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: 15 May 2017
Date Tested: 17 May 2017
Date Test Completed: 17 May 2017
Purchase Order: 28905

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0035558/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 15/05/2017
Test Article: Clearklens IPA
Sample Code: FMP17115 42464
Batch Ref: 8463
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 | 57 % |
| Dilution Tested | MM110/04 | 1/40 |
| Endotoxin Spike Level | MM110/02 | 0.5 EU/mL |
| Tested in Accordance with Ph Eur, USP & JP | MQ005/07 | EP 9.0 2.6.14, USP 40 <85> & JPXVII 4.01 |
| Product Standard Data Sheet | FG047/psd | FM02 |

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

BSc. CBiol. MRSB

Date: 18 May 2017 18:02:29

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



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
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Date Received: 15 May 2017
Date Tested: 23 May 2017
Date Test Completed: 06 Jun 2017
Purchase Order: 28905

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0035558/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 15/05/2017
Test Article: Clearklens IPA
Sample Code: FMP17115 42464
Batch Ref: 8463
Qty Received: 20 x 900mL Bottles + 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 |
| Tested in Accordance with Ph Eur, USP & JP | MQ005/07 | see external comments |
| Product Standard Data Sheet | FG047/psd | FM03 |

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the volume tested does not comply with the requirements of the current Pharmacopoeias.

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

 C. Moore MMSB

Date: 07 Jun 2017 12:33:03

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology