



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 6.07.2016

| | |
|-----------------|--------------------|
| Product Name | CLEARKLENS IPA VH1 |
| Product Code | 100885705 |
| Batch Number | FHP 16146 40410 |
| Production Date | 25/05/2016 |
| Expiration Date | Exp. 25/05/2018 |

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 : | <i>Alina, Pautyishko</i> |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

COA 100885705

Version : 02

Date of issuing : April 7th 2016



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 04-Jul-2016

UK32S11641950-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 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: | 1002734 |
| Customer Reference Number: | P026716 |
| Product Description: | JD IPA BOTTLES 25-45kGy |
| Validation Reference: | 4.1971 |
| Quantity Received: | 702 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 690 X B/NO FMP16146 40410 + 12 SAMPLES THU 9TH JUNE 2016 13 PLTS LOT 3 |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 02-Jul-2016 06:17 |
| Reference Dose Range kGy: | 35.7 - 37.5 |
| Calculated Minimum Dose kGy: | 25.7 |
| Calculated Maximum Dose kGy: | 38.9 |

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

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
Fax: +44(0)1329 226688

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: 07 Jul 2016
Date Tested: 11 Jul 2016
Date Test Completed: 11 Jul 2016
Purchase Order: 26897

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029865/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 07/07/2016
Test Article: Clearklens IPA
Sample Code: FMP16146 40410
Batch Ref: 7608
Qty Received: 1 x 900mL Bottles

| Test | Method Item | Result |
|--|-------------|---|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00 | <0.2 EU/mL |
| Spiked Recovery | MM110/01 | 73 % |
| 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 8.0 2.6.14, USP 39 <85> & JPXVI 4.01 |
| Product Standard Data Sheet | FG047/psd | FM02 |

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

Date: 12 Jul 2016 14:34:12

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Fax: +44(0)1329 226688

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: 07 Jul 2016
Date Tested: 10 Jul 2016
Date Test Completed: 24 Jul 2016
Purchase Order: 26897

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0029865/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 07/07/2016
Test Article: Clearklens IPA
Sample Code: FMP16146 40410
Batch Ref: 7608
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.

Date: 25 Jul 2016 15:07:04

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Solutions in Healthcare Contract
Manufacture & Packing

VAT Registration No: GB 534 5276 43

Flexible Medical Packaging Ltd
Unit 8, Hightown
White Cross Industrial Estate
Lancaster
Lancashire, LA1 4XS

01524 68737
01524 67110
sales@flexible-medical.com
www.flexible-medical.com

CERTIFICATE OF CONFORMANCE



TO:
Diversey Ltd
Amber Park Distribution Centre
Highview Road
South Normanton, Alfreton
Derbyshire
DE55 2DT

Page : 1

DATE :15/07/16
DESPATCH NO :DN36473
FMP ORDER NUMBER :SO27948
CUSTOMER REFERENCE :4701842863/100885705

| LINE | PART NUMBER | CUSTOMER REFERENCE | QUANTITY | UNIT | LOT REF | LOT LINE |
|------|-------------|--------------------|----------|------|---------|----------|
|------|-------------|--------------------|----------|------|---------|----------|

| | | | | | | |
|---|-----------|-----------|-----|----|---------|--|
| 1 | DEV001928 | 100885705 | 690 | EA | WO40410 | |
| CLEARKLENS IPA (ITALY) 900ML 6 UNIT BOTTLE PK | | | | | | |
| ITEM REF:1002734/ DOSE: 25-45KGY / VAL:4.1971 | | | | | | |
| BATCH NO: FMP16146 40410 | | | | | | |
| Labelled with UN LQ | | | | | | |

CERTIFICATE OF CONFORMANCE

These goods have been manufactured in accordance with FMP Quality Systems (ISO9001:2008, ISO13485:2003, ISO14001:2004) and to the agreed specification. Responsibility for release of sterile products remains with the customer. Customers are responsible for ensuring the fitness for the purpose of the goods supplied.

FOR AND ON BEHALF OF FMP Q.A. DEPARTMENT: _____

DATE: 15/07/16



FMP® is a CliniMed® Group Company

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