



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 7/7/14

| | |
|-----------------|--------------------|
| Product Name | CLEARKLENS IPA VH1 |
| Product Code | 7513400 |
| Batch Number | FMP14160 36187 |
| Production Date | 06/2014 |
| Expiration Date | 06/2016 |

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 : | Chitra, Mathure |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

COA 7513400

Version : 03

Date of issuing : November 28th 2011



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 03-Jul-2014

UK32S11182884-1-2

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: | P022395 |
| Product Description: | JD IPA BOTTLES 25-45kGy |
| Validation Reference: | 4.0621 |
| Quantity Received: | 708 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | 704 X B/NO:FMP14160 36187 + 4 SAMPLES MON 16.06.14 13PLTS |
| Other Process Details: | Released against validation 4.1723, calculated minimum dose 25.8 kGy and calculated maximum dose 40.3 kGy |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 28-Jun-2014 09:29 |
|-------------------------------|-------------------|

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

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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 2014
Date Tested: 09 Jul 2014
Date Test Completed: 23 Jul 2014
Purchase Order: PO22537

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017503/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP
Date Received: 07/07/2014
Test Article: Clearlens IPA Block 1
Sample Code: 5574
Batch Ref: FMP14160 36187
Qty Received: 21 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: 24 Jul 2014 14:32:52

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0017503

Certificate of Analysis - OSMM

Print Number: P0021497

Page 1 of 1

ISO
17025

GLP GMP FDA

Company Registered in England No. 752951 Wickham Laboratories Limited,
Registered Office: Hoeford Point, Barwell Lane, Gosport, Hampshire



Wickham Laboratories

Contract Analytical Services

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
Telephone: +44(0)1329 226600
Alt. Telephone: +44(0)1329 832511
Fax: +44(0)1329 832511

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 2014
Date Tested: 08 Jul 2014
Date Test Completed: 08 Jul 2014
Purchase Order: 22537

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0017503/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP
Date Received: 07/07/2014
Test Article: Clearlens IPA Block 1
Sample Code: 5574
Batch Ref: FMP14160 36187
Qty Received: 1 Bottle

| Test | Method Item | Result |
|---|-------------|------------|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00 | <0.2 EU/mL |
| Spiked Recovery | MM110/01 | 63 % |
| 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: 11 Jul 2014 15:43:24

Mr K.A. Barker
Business Manager - Microbiology

Consignment: 0017503

Certificate of Analysis - OSMM

Print Number: P0021230

Page 1 of 1

ISO
17025

GLP GMP FDA

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