



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 20.03.17

| | |
|-----------------|--------------------|
| Product Name | CLEARKLENS DE VH29 |
| Product Code | 100862174 |
| Batch Number | FMP 17058 42073 |
| Production Date | 27/02/2017 |
| Expiration Date | EXP 27/02/2019 |

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 | 0.880 | 0.888 | 0.884 |
| | | | | |
| | | | | |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | Parvinder, H. H. H. |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|---|
| COA 7515783 | Version : 04 | Date of issuing : April 27 th 2012 |
|-------------|--------------|---|



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: 21 Mar 2017
Date Tested: 23 Mar 2017
Date Test Completed: 06 Apr 2017
Purchase Order: 28594

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034559/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 21/03/2017
Test Article: Clearklens DE
Sample Code: FMP17058 42073
Batch Ref: 8319
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 |
| 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: 07 Apr 2017 11:01:17

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

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Date Received: 21 Mar 2017
Date Tested: 22 Mar 2017
Date Test Completed: 22 Mar 2017
Purchase Order: 28594

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034559/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 21/03/2017
Test Article: Clearlens DE
Sample Code: FMP17058 42073
Batch Ref: 8319
Qty Received: 1 x 900mL Bottle

| Test | Method Item | Result |
|--|-------------|--|
| Bacterial Endotoxin by Kinetic QCL Test | MM110/00 | <0.25 EU/mL |
| Spiked Recovery | MM110/01 | 65 % |
| Dilution Tested | MM110/04 | 1/50 |
| 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 39 <85> & JPXVII 4.01 |
| Product Standard Data Sheet | FG047/psd | FM01 |

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

Date: 23 Mar 2017 09:49:10

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 10-Mar-2017

UK33S11828801-1-1

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: | 1106483 |
| Customer Reference Number: | P028518 |
| Product Description: | DIVER DE BLK2 BOTTLE DV4648 25-45kGy |
| Validation Reference: | 4648 |
| Quantity Received: | 702 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 45.0 |
| Customer Unit Lot/Batch Number: | FMP17058 42073, Inc 4 samples, 13 PLTS |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 10-Mar-2017 05:45 |
| Reference Dose Range kGy: | 35.6 - 36.0 |
| Calculated Minimum Dose kGy: | 28.1 |
| Calculated Maximum Dose kGy: | 40.7 |

Irradiation Release Authorised By Synergy Health plc

A2

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