



Diversey Europe BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 24/2/14

| | |
|-----------------|-----------------------------|
| Product Name | CLEARKLENS TEGO 2000SC VH25 |
| Product Code | 7513387 |
| Batch Number | FMP14041 35731 |
| 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 Slightly Yellow Liquid | | Clear Slightly Yellow Liquid |
| pH 100% (20°C) | JDM001 | 7.5 | 8.5 | 7.7 |
| Specific Gravity (20°C) | JDM004 | 0.993 | 1.003 | 0.998 |
| | | | | |

| | | |
|---|----------|---------------------------|
| On behalf of Diversey site Quality Manager | Name : | Amalena |
| | Position | Quality Control Inspector |

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|--|
| COA 7513387 | Version : 03 | Date of issuing : November 28 th 2011 |
|-------------|--------------|--|



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 15-Feb-2014

UK32S11112834-1-1

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: | 1002722 |
| Customer Reference Number: | P021775 |
| Product Description: | DIVERSEY TEGO 2000SC 50ml 25-42kGy |
| Validation Reference: | 4.0716 |
| Quantity Received: | 45 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 42.0 |
| Customer Unit Lot/Batch Number: | LOT 1; 1 PLT; THUR 13.02.14; 43 x B/NO. FMP14041 35731 + 2 SAMPLES |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 15-Feb-2014 15:06 |
| Reference Dose Range kGy: | 33.2 - 33.8 |
| Calculated Minimum Dose kGy: | 27.6 |
| Calculated Maximum Dose kGy: | 37.2 |

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
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Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 24 Feb 2014
Date Tested: 04 Mar 2014
Date Test Completed: 26 Mar 2014
Purchase Order: 21820

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0015087/1
Test Required: Sterility Test by Membrane Filtration (Steritest) Method I with Subculture:
PH Eur and USP
Date Received: 24/02/2014
Test Article: TEGO 2000sc Block 1
Sample Code: 454722
Batch Ref: FMP14041 35731
Qty Received: 20 x 50mL 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 two broths |
| Growth in Fluid Thioglycollate Medium at 30-35°C after 14 days | MM107/02 | No growth in two broths |
| Growth of Sub-culture in Tryptone Soya Broth at 30-35°C after 4 days | MM107/07 | No growth in two broths |
| Growth of Sub-culture in Fluid Thioglycollate at 20-25°C after 4 days | MM107/08 | No growth in two broths |
| Volume Tested | MM107/05 | 20 x 50 mL |
| Product Standard Data Sheet | FG047/psd | FM08 |

Comments

Corrected Certificate of Analysis to LR0015087/1 authorised 27 March 2014, incorrect test article details supplied.
Test carried out according to current Pharmacopoeias.

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

Date: 14 Apr 2014 11:55:08

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

Consignment: 0015087

Certificate of Analysis - OSMM

Print Number: P0019147

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ISO
17025

GLP GMP FDA

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