



Diversey Europe BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 16.03.2017

| | |
|-----------------|-------------------------------|
| Product Name | CLEARLENSE CLEANSINALE SC VH9 |
| Product Code | 7516429 |
| Batch Number | FNP17075 42155 |
| Production Date | 16.03.2017 |
| Expiration Date | EXP 16/03/2019 |

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 | Slightly Yellow Liquid | clear slightly yellow liquid |
| pH (100% 20°C) | JDM001 | 12.0 | 13.0 | 13.0 |
| Specific Gravity (20°C) | JDM004 | 1.040 | 1.060 | 1.052 |
| | | | | |

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

This document being issued electronically does not bear a signature

| | | |
|-------------|--------------|--|
| COA 7516429 | Version : 03 | Date of issuing : November 28 th 2011 |
|-------------|--------------|--|



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: 22 Mar 2017
Date Tested: 28 Mar 2017
Date Test Completed: 11 Apr 2017
Purchase Order: 28606

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0034582/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 22/03/2017
Test Article: Cleansinald sc
Sample Code: FMP17075 42155
Batch Ref: 560747
Qty Received: 20 x 25mL 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 25 mL |
| Tested in Accordance with Ph Eur, USP & JP | MQ005/07 | EP 9.0 2.6.1. USP 39 <71> & JP XVII 4.06 |
| Product Standard Data Sheet | FG047/psd | FM06 |

Comments

Corrected Certificate of Analysis to LR 0034582/1 authorised 12.04.17 due to addition of batch number.

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

 CMOORE, MMSB

Date: 12 Apr 2017 14:17:44

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 01-Mar-2017

UK32S11821168-1-1

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: | 1002719 |
| Customer Reference Number: | P028453 |
| Product Description: | C/SINALD BLK BOTT/CAPS/BAGS 25-40kGy |
| Validation Reference: | 4.1666 |
| Quantity Received: | 33 |
| Customer Minimum Specification kGy: | 25.0 |
| Customer Maximum Specification kGy: | 40.0 |
| Customer Unit Lot/Batch Number: | 11 X WO42048,11 X WO42156,11 X WO42213 MON 27 FEB 2017 6 PLTS |

Irradiation Data

| | |
|-------------------------------|-------------------|
| Date and Time of Irradiation: | 01-Mar-2017 00:55 |
| Reference Dose Range kGy: | 33.8 - 34.3 |
| Calculated Minimum Dose kGy: | 27.3 |
| Calculated Maximum Dose kGy: | 35.3 |

Items irradiated under WO42156 are to be used in finished product batch FMP17075 42155

CRS
24/03/17

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