



Diversey Europe Operations BV

Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 09.05.2017

Product Name	CLEARKLENS DE VH29
Product Code	100862174
Batch Number	FNP17102 42461
Production Date	12/04/2017
Expiration Date	EXP 12/04/2019

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	0.888

On behalf of Diversey site Quality Manager	Name :	J. Stawon, P. Tyjse
	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
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 28-Apr-2017

UK33S11862863-1-1

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:	28822
Product Description:	DIVER DE BLK2 BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	685
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17102, 42461, INCLUDING 4 SAMPLES, 13PLTS

Irradiation Data

Date and Time of Irradiation:	28-Apr-2017 00:11
Reference Dose Range kGy:	35.1 - 36.6
Calculated Minimum Dose kGy:	27.7
Calculated Maximum Dose kGy:	41.4

Irradiation Release Authorised By Synergy Health plc

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



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 10 May 2017
Date Tested: 18 May 2017
Date Test Completed: 01 Jun 2017
Purchase Order: 28878

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0035485/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/05/2017
Test Article: Clearklens DE
Sample Code: 8456
Batch Ref: FMP17102 42461
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	EP 9.0 2.6.1, USP 40 <71> & JP XVII 4.06
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.

CBiol MNSB

Date: 02 Jun 2017 11:52:49

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
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LA1 4XS

Date Received: 10 May 2017
Date Tested: 15 May 2017
Date Test Completed: 15 May 2017
Purchase Order: 28878

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0035485/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 10/05/2017
Test Article: Clearklens DE
Sample Code: 8456
Batch Ref: FMP17102 42461
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	78 %
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 40 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM01

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

BSc, CBiol, MRSB

Date: 16 May 2017 10:32:29

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology