



Diversey Europa BV

Maarssebroekdijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 24.01.17

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 17009 - 41867
Production Date	09/01/2017
Expiration Date	EXP 09/01/2019

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	0.872	0.883	0.880

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

This document being issued electronically does not bear a signature

COA 7513400	Version : 03	Date of issuing : November 28 th 2011
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<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 14-Jan-2017

UK33S11788517-1-1

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:	1104747
Customer Reference Number:	P028095
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	382
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, FMP17009 41867, 4 BOXES OF SAMPLES, 7 PLTS

Irradiation Data

Date and Time of Irradiation:	14-Jan-2017 01:49
Reference Dose Range kGy:	36.3 - 36.7
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	41.5

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



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 31-Jan-2017

UK33S11798348-1-1

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

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UNITED KINGDOM

All in accordance with current Technical Agreement

Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1104747
Customer Reference Number:	28169
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	1033
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, FMP17009 41867, 19PLTS

Irradiation Data

Date and Time of Irradiation:	27-Jan-2017 10:48
Reference Dose Range kGy:	35.2 - 36.9
Calculated Minimum Dose kGy:	27.8
Calculated Maximum Dose kGy:	41.8

Irradiation Release Authorised By Synergy Health plc

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Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
Flexible Medical Packaging Limited
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Date Received: 24 Jan 2017
Date Tested: 26 Jan 2017
Date Test Completed: 26 Jan 2017
Purchase Order: 28175

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0033441/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 24/01/2017
Test Article: Clearklens IPA
Sample Code: FMP17009 41867
Batch Ref: 8202
Qty Received: 1 x 900mL Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	82 %
Dilution Tested	MM110/04	1/40
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	FM02

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

Date: 27 Jan 2017 09:32:51

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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Date Received: 24 Jan 2017
Date Tested: 01 Feb 2017
Date Test Completed: 15 Feb 2017
Purchase Order: 28175

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0033441/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 24/01/2017
Test Article: Clearklens IPA
Sample Code: FMP17009 41867
Batch Ref: 8202
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	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: 16 Feb 2017 12:17:18

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology