



Diversey Europe BV
Maarssebroeksedijk 2
3542 DN Utrecht
The Netherlands
Tel. +31 (0)30 247 8427

CERTIFICATE OF ANALYSIS

Date: 25.08.2016

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 16208 40978
Production Date	26/07/2016
Expiration Date	EXP 26/07/2018

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 :	Patrycja J. Stanek
	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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Wickham Laboratories

Contract Analytical Services

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

Date Received: 25 Aug 2016
Date Tested: 31 Aug 2016
Date Test Completed: 14 Sep 2016
Purchase Order: 27213

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0030765/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 25/08/2016
Test Article: Clearklens IPA
Sample Code: FMP16208 40978
Batch Ref: 7823
Qty Received: 20 x 900mL Bottle + 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: 15 Sep 2016 14:29:43

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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Date Received: 25 Aug 2016
Date Tested: 26 Aug 2016
Date Test Completed: 26 Aug 2016
Purchase Order: 27213

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0030765/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 25/08/2016
Test Article: Clearklens IPA
Sample Code: FMP16208 40978
Batch Ref: 7823
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	53 %
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 8.0 2.6.14, USP 39 <85> & JPXVI 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 30 Aug 2016 10:54:39

Mr K.A. Barker
Business Manager – Projects



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 08-Aug-2016

UK33S11679341-1-1

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:	P027097
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	706
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, FMP16208, W/O No. 40978, 13 PLTS

Irradiation Data

Date and Time of Irradiation:	07-Aug-2016 20:26
Reference Dose Range kGy:	36.3 - 37.4
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	42.3

Irradiation Release Authorised By Synergy Health plc

A3

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: 14-Aug-2016

UK33S11684359-1-1

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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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:	P027127
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	712
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	DEV001152, FMP16208, 40978, 13 PLTS

Irradiation Data

Date and Time of Irradiation:	14-Aug-2016 07:04
Reference Dose Range kGy:	37.0 - 38.1
Calculated Minimum Dose kGy:	29.2
Calculated Maximum Dose kGy:	43.1

Irradiation Release Authorised By Synergy Health plc

17-Aug-2016 Version A2 170816 CE

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