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CERTIFICATE OF ANALYSIS

Date: 12/02/2018

Product Name	CLEARLENs IPA VH1
Product Code	100885705
Batch Number	FMP18025 44373
Production Date	25/01/2018
Expiration Date	EXP 25/01/2020

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)	DM004	0.872	0.883	0.876

On behalf of Diversey site Quality Manager	Name :	ll. Kavabuda, Pantyislo
	Position	Quality Control Inspector

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COA Template	Version : 02	Date of issuing : November 24 th 2017
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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: 13 Feb 2018
Date Tested: 21 Feb 2018
Date Test Completed: 07 Mar 2018
Purchase Order: 30466

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040845/5
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 13/02/2018
Test Article: Clearklens IPA
Sample Code: FMP18025 44373
Batch Ref: 9080
Qty Received: 20 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.

 BSc, CBiol, MRSB

Date: 09 Mar 2018 11:21:43

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



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Date Received: 13 Feb 2018
Date Tested: 15 Feb 2018
Date Test Completed: 15 Feb 2018
Purchase Order: 30466

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0040845/6
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 13/02/2018
Test Article: Clearklens IPA
Sample Code: FMP18025 44373
Batch Ref: 9080
Qty Received: 1 Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	86 %
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 9.3 2.6.14, USP 40<85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

BSc, CBiol, MRSB

Date: 16 Feb 2018 09:04:09

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 13-Feb-2018

UK33S12057025-1-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

Flexble 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:	P030455
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	171
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18025 44373, 3 plts

Irradiation Data

Date and Time of Irradiation:	13-Feb-2018 08:46
Reference Dose Range kGy:	36.4 - 37.1
Calculated Minimum Dose kGy:	28.8
Calculated Maximum Dose kGy:	42.0

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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.steris-ast.com>

Certificate of Irradiation

Date Issued: 06-Feb-2018

UK33S12053264-2-1

This is to certify that AST Daventry Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 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:	P030417
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	545
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18025 44373, INC 5 SAMPLES, 10 pils

Irradiation Data

Date and Time of Irradiation:	06-Feb-2018 01:06
Reference Dose Range kGy:	37.2 - 38.0
Calculated Minimum Dose kGy:	29.4
Calculated Maximum Dose kGy:	43.0

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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