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CERTIFICATE OF ANALYSIS

Date: 09/04/2018

Product Name	CLEARLENs IPA VH1
Product Code	7513400
Batch Number	FMP 18074 44723
Production Date	15/03/2018
Expiration Date	EXP 15/03/2020

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 :	Patyiska, Karabina
	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: 10 Apr 2018
Date Tested: 25 Apr 2018
Date Test Completed: 09 May 2018
Purchase Order: 30768

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0041945/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 10/04/2018
Test Article: Clearlens IPA
Sample Code: FMP18074 44723
Batch Ref: 9208
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 MRSB

Date: 10 May 2018 08:11:05

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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Date Received: 10 Apr 2018
Date Tested: 11 Apr 2018
Date Test Completed: 11 Apr 2018
Purchase Order: 30768

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0041945/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 10/04/2018
Test Article: Clearklens IPA
Sample Code: FMP18074 44723
Batch Ref: 9208
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	77 %
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.

CBio: MKSB

Date: 11 Apr 2018 15:19:25

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology



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

Certificate of Irradiation

Date Issued: 28-Mar-2018

UK33S12080357-3-1

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

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:	P030700
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	491
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18074 44723, INC 5 SAMPLES, 9 pils

Irradiation Data

Date and Time of Irradiation:	28-Mar-2018 07:32
Reference Dose Range kGy:	35.9 - 35.9
Calculated Minimum Dose kGy:	28.4
Calculated Maximum Dose kGy:	40.6

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 Steelworks, 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: 13-Apr-2018

UK33S12084441-1-1

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

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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:	P030733
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	935
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP18074 44723, 18 pils
Other Process Details:	This product has received an overdose

Irradiation Data

Date and Time of Irradiation:	31-Mar-2018 07:01
Reference Dose Range kGy:	34.5 - 40.3
Calculated Minimum Dose kGy:	27.3
Calculated Maximum Dose kGy:	45.6

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

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