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CERTIFICATE OF ANALYSIS

Date: 03/01/2018

Product Name	CLEARKLENS IPA VH1		
Product Code	1008857-05		
Batch Number	FMP 17339, 43822		
Production Date	05 12 2017		
Expiration Date	EXP 05/12/12019		

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	Lin	nits	Results
		Lower	- Upper	
	Visual	Clear Colourless		Clear Colour
Appearance		Liquid		less Liquid
Specific Gravity (20°C)	DM004	0.872	0.883	0.880

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

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CC	OA Template	Version: 02	Date of issuing : November 24 th 2017



http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 18-Dec-2017

UK33S12030190-2-1

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

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 100432 **Account Number: Synergy Health Sales Part Reference:** 1104747 P030170 **Customer Reference Number: IPA BOTTLE DV4648 25-45kGy Product Description:** Validation Reference: 4648 706 **Quantity Received:** 25.0 Customer Minimum Specification kGy: **Customer Maximum Specification kGy:** 45.0 FMP17339 43822, INC 4 SAMPLES, 13 plts **Customer Unit Lot/Batch Number:** irradiation Data 18-Dec-2017 19:06 Date and Time of Irradiation: Reference Dose Range kGy: 35.9 - 36.8 28.4 Calculated Minimum Dose kGy: 41.6 Calculated Maximum Dose kGy:

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



Wickham Laboratories Ltd Hoeford Point, Barwell Lane, Gosport Hampshire PO13 0AU England

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mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster **LA14XS**

Date Received:

05 Jan 2018

Date Tested:

10 Jan 2018

Date Test Completed:

24 Jan 2018

Purchase Order:

30202

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0040133/1

Test Required:

Sterility by Membrane Filtration Steritest

Date Received: Test Article:

05/01/2018

Clearklens IPA FMP17339 43822

Sample Code: **Batch Ref:**

9001

Qtv Received:

20 x 900mL + 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.

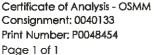
Approval is provided by Electronic Signature. Their name and position is shown below.

CBiol MIKSB

Date: 25 Jan 2018 12:52:29

Mrs C Moore

Laboratory Manager - Pharmaceutical Microbiology









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Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

05 Jan 2018

Date Tested:

10 Jan 2018

Date Test Completed:

10 Jan 2018

Purchase Order:

30202

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0040133/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL

Date Received:

05/01/2018

Test Article:

Clearkiens IPA FMP17339 43822

Sample Code: Batch Ref:

9001

9001

Qty Received:

1 x 900mL

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. CSIOL MRSB

Date: 11 Jan 2018 09:17:18

Mrs P. Pham-Lengoc

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0040133 Print Number: P0048180 Page 1 of 1

