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CERTIFICATE OF ANALYSIS

Date: 27.02.2019

Product Name	**CLEARKLENS IPA VH1**
Product Code	101100418
Batch Number	FMP19042, 46912
Production Date	11/02/2019
Expiration Date	EXP 11/02/2021

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 Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872 0.883	0.877

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

This document being issued electronically does not bear a signature

COA Template	*Version : 02*	*Date of issuing : November 24th 2017*

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1751A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19042 46912	386	Case

Validation Reference Number: 4648

Processing Run Start Date: 25-Feb-19 07:08 PM

Processing Run End Date: 26-Feb-19 03:58 AM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**28.1**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**41.4**

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
NN11 8RB
Phone: + 44(0) 1327 706 111

STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-1621A

Product Code	Lot Number	Quantity	UOM
IPA BOTTLE DV4648	FMP19042 46912	324	Case
Validation Reference Number: 4648			
IPA BOTTLE DV4648	FMP19042 46912 INC5XSAMPLES	5	Case
Validation Reference Number: 4648			

PO Number: PO32591

Processing Run Start Date: 17-Feb-19 04:40 AM

Processing Run End Date: 17-Feb-19 01:33 PM

Specified Dose Range (kGy):	**25.0 - 45.0**	**Calculated Min Dose (kGy):**	**27.3**
Reference Dose Range (kGy):	**31.6- 39.8**	**Calculated Max Dose (kGy):**	**40.4**

Other Information

FMP19042 46912, INC 5 SMPLS, 6 PLTS

Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-02-18 08:41 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
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NN11 8RB
Phone: + 44(0) 1327 706 111

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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
LA1 4XS

Date Received: 26 Feb 2019
Date Tested: 19 Mar 2019
Date Test Completed: 02 Apr 2019
Purchase Order: 32656

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0047421/2
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 26/02/2019
Test Article: Clearklens IPA
Sample Code: FMP19042 46912
Batch Ref: 9952
Qty Received: 20 x 900mL Bottles + 2 x 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	FM03-01

Comments

The testing procedure was performed in compliance with the current Pharmacopoeias however, the quantity 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: 05 Apr 2019 09:14:25

Mrs P. Pham-Lengoc
Documentation Manager – Microbiology

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Lancaster
LA1 4XS

Date Received: 26 Feb 2019
Date Tested: 27 Feb 2019
Date Test Completed: 27 Feb 2019
Purchase Order: 32656

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0047421/1
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 26/02/2019
Test Article: Clearklens IPA
Sample Code: FMP19042 46912
Batch Ref: 9952
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	85 %
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 41 <85> & JPXVII 4.01
Product Standard Data Sheet	FG047/psd	FM02-01

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

Watson

Date: 28 Feb 2019 15:33:39

Victoria Watson
Laboratory Manager – Microbiology