

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 20/09/18

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	FMP 18234 45640
Production Date	22/08/2018
Expiration Date	EXP2210812020

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 Col Liqu		Clear Colour
Specific Gravity (20°C)	DM004	0.872	0.883	0.876

On behalf of Diversey site Quality Manager	Name :	Partyrists 1 (workersia
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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



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Ms D Henderson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

21 Sep 2018

Date Tested:

28 Sep 2018

Date Test Completed:

12 Oct 2018

Purchase Order:

PO31766

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0044872/5

Test Required:

Sterility by Membrane Filtration Steritest

Date Received: Test Article: Sample Code: 21/09/2018 Clearklens IPA

FMP18234 45640

Batch Ref: 9612

Qty Received: 20 x 900mL Bottles

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 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.

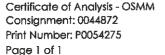
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CHEE MIRSH

Date: 15 Oct 2018 15:16:16

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 LA14XS

Date Received:

21 Sep 2018

Date Tested:

24 Sep 2018

Date Test Completed:

27 Sep 2018

Purchase Order:

PO31766

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0044872/6

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL

Date Received:

21/09/2018

Test Article:

Clearklens IPA FMP18234 45640

Sample Code: **Batch Ref:**

9612

Qty Received:

1 x 900mL Bottles

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	58 %
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.

BSc. CBiol. MRSB

Date: 27 Sep 2018 15:29:34

Mrs P. Pham-Lengoc

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - OSMM Consignment: 0044872 Print Number: P0053901 Page 1 of 1





http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 10-Sep-2018

UK33S12159527-1-1

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

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:** P031644 **Product Description: IPA BOTTLE DV4648 25-45kGy** Validation Reference: 4648 **Ouantity Received:** 713 **Customer Minimum Specification kGy:** 25.0 **Customer Maximum Specification kGy: Customer Unit Lot/Batch Number:** FMP18234 45640, INC 5 SMPLS, 13 PLTS **Irradiation Data** Date and Time of Irradiation: 09-Sep-2018 15:54 Reference Dose Range kGy: 32.6 - 35.5 Calculated Minimum Dose kGy: 25.8 Calculated Maximum Dose kGy: 40.2

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