Diversey Europe Operations BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 21.06.2017

Product Name	CLEARKLENS IPA VH1
Product Code	100885705
Batch Number	FHP 17143 42638
Production Date	23/05/2017
Expiration Date	Exp. 23/05/2019

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)	JDM004	0.872 0.883	0.876

On behalf of Diversey site Quality Manager	Name :	Olga Kucnna, Partyka
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

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Certificate of Irradiation

Date Issued: 09-Jun-2017 UK33S11891319-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 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:	P029034
Product Description:	IPA BOTTLE DV4648 25-45kGy
Validation Reference:	4648
Quantity Received:	707
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	FMP17143 42638, INC 4 SAMPLES, 13 PLTS

Irradiation Data

Date and Time of Irradiation:	09-Jun-2017 13:59
Reference Dose Range kGy:	37.9 - 39.6
Calculated Minimum Dose kGy:	30.0
Calculated Maximum Dose kGy:	44.8

Irradiation Release Authorised By Synergy Health plc

Wickham Laboratories Ltd
Hoeford Point, Barwell Lane, Gosport
Hampshire PO13 0AU England
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www.wickhamlabs.co.uk

Ms D Henderson
Flexible Medical Packaging Limited
Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 20 Jun 2017
Date Tested: 22 Jun 2017
Date Test Completed: 22 Jun 2017
Purchase Order: 29103

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0036229/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 20/06/2017
Test Article: Clearklens IPA
Sample Code: FMP17143 42638
Batch Ref: 8600
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	80 %
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 9.0 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: 23 Jun 2017 12:14:43

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

GMP GLP FDA

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Date Received: 20 Jun 2017
Date Tested: 22 Jun 2017
Date Test Completed: 06 Jul 2017
Purchase Order: 29103

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0036229/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 20/06/2017
Test Article: Clearklens IPA
Sample Code: FMP17143 42638
Batch Ref: 8600
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	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.

Date: 07 Jul 2017 11:00:01

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology