Diversey Europa BV

Maarssenbroeksedijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 8427

CERTIFICATE OF ANALYSIS

Date: 01.03.2016

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	FMP 16035 39698
Production Date	04/02/2016
Expiration Date	EXP 04/02/2018

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	0.879

On behalf of Diversey site Quality Manager	Name :	Pantyusha M.
	Position	Quality Control Inspector

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Certificate of Irradiation

Date issued: 17-Feb-2016 **UK32S11562554-1-1**

This is to certify that Bradford 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:	1002734
Customer Reference Number:	PO25956
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	709
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	705 X BATCH NO: FMP16035 39698 + 4 SAMPLES THURS 11TH FEB 2016 13 PLTS LOT 4

Irradiation Data

Date and Time of Irradiation:	17-Feb-2016 23:14
Reference Dose Range kGy:	37.1 - 37.6
Calculated Minimum Dose kGy:	26.7
Calculated Maximum Dose kGy:	39.0

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: 23 Feb 2016
Date Tested: 24 Feb 2016
Date Test Completed: 24 Feb 2016
Purchase Order: 26058

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0027449/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 23/02/2016
Test Article: Clearklens IPA
Sample Code: FMP16035 39698
Batch Ref: 7346
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	84 %
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 8.0 2.6.14, USP 38 <85> & JPXVI 4.01
Product Standard Data Sheet	FG047/psd	FM02

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

Date: 25 Feb 2016 11:23:04

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology

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Ms D Henderson
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Date Received: 23 Feb 2016
Date Tested: 01 Mar 2016
Date Test Completed: 15 Mar 2016
Purchase Order: 26058

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0027449/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 23/02/2016
Test Article: Clearklens IPA
Sample Code: FMP16035 39698
Batch Ref: 7346
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: 16 Mar 2016 12:55:28

Mrs C Moore
Laboratory Manager - Pharmaceutical Microbiology