



Diversey Europe BV

Maarssebroekdijk 2
3542 DN Utrecht
The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 9/2/16

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FMP16012 39697
Production Date	12/01/2016
Expiration Date	GXP12/01/2018

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		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		Clear colourless liquid
Specific Gravity (20°C)	JDM004	0.872	0.883	0.875

On behalf of Diversey site Quality Manager	Name :	C. Piscoe, P. P. P. P.
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA 7513400

Version : 03

Date of issuing : November 28th 2011



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 01-Feb-2016

UK32S11553301-1-1

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:	P025855
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	717
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	713 X BATCH NO: FMP16012 39697 + 4 SAMPLES THURS 28TH JAN 2016 14 PLTS

Irradiation Data

Date and Time of Irradiation:	01-Feb-2016 10:51
Reference Dose Range kGy:	36.1 - 38.5
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	40.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date issued: 01-Feb-2016

UK32S11549031-1-1

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

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Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002734
Customer Reference Number:	P025807
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	702
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BATCH NO: FMP16012 39697 THURS 21ST JAN 2016 13 PLTS LOT 3

Irradiation Data

Date and Time of Irradiation:	31-Jan-2016 23:45
Reference Dose Range kGy:	37.6 - 38.6
Calculated Minimum Dose kGy:	27.1
Calculated Maximum Dose kGy:	40.1

Irradiation Release Authorised By Synergy Health plc

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM
Company Registered In England and Wales No: 01771333 VAT Number: GB 813038069



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
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White Cross Industrial Estate
Lancaster
LA1 4XS

Date Received: 04 Feb 2016
Date Tested: 15 Feb 2016
Date Test Completed: 29 Feb 2016
Purchase Order: 25920

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0027093/1
Test Required: Sterility by Membrane Filtration Steritest
Date Received: 04/02/2016
Test Article: Clearklens IPA
Sample Code: FMP16012 39697
Batch Ref: 7287
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 supplied does not comply with the requirements of the current Pharmacopoeias.

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

Date: 01 Mar 2016 14:30:51

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology



Wickham Laboratories

Contract Analytical Services

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Ms D Henderson
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Date Received: 04 Feb 2016
Date Tested: 08 Feb 2016
Date Test Completed: 08 Feb 2016
Purchase Order: 25920

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0027093/2
Test Required: Bacterial Endotoxin Testing by Kinetic QCL
Date Received: 04/02/2016
Test Article: Clearklens IPA
Sample Code: FMP16012 39697
Batch Ref: 7287
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	112 %
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: 08 Feb 2016 15:12:31

Mrs P. Pham-Lengoc
Laboratory Manager - Pharmaceutical Microbiology