



Diversey Europa BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 27.11.2015

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	FMP 15295 39094
Production Date	22/10/2015
Expiration Date	22/10/2017

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	0.879

On behalf of Diversey site Quality Manager	Name :	Parkyides, J. Staver
	Position	Quality Control Inspector

*This document being issued electronically does not bear a signature*

COA 7514372	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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<http://www.synergyhealthplc.com>

# Certificate of Irradiation

Date Issued: 21-Nov-2015

UK32S11496227-1-1

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

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## Order Information

Account Number:	100432
Synergy Health Sales Part Reference:	1002734
Customer Reference Number:	P025402
Product Description:	JD IPA BOTTLES 25-45kGy
Validation Reference:	4.1971
Quantity Received:	700
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	BATCH NO FMP15295 39094 THURS 29TH OCT 2015 13 PLTS LOT 1 + 4 SAMPLES

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## Irradiation Data

Date and Time of Irradiation:	21-Nov-2015 13:13
Reference Dose Range kGy:	36.8 - 39.5
Calculated Minimum Dose kGy:	26.5
Calculated Maximum Dose kGy:	41.0

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Irradiation Release Authorised By Synergy Health plc

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

**Date Received:** 26 Nov 2015  
**Date Tested:** 27 Nov 2015  
**Date Test Completed:** 27 Nov 2015  
**Purchase Order:** 25557

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0026049/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 26/11/2015  
**Test Article:** ClearKlens IPA  
**Sample Code:** FMP15295 39094  
**Batch Ref:** 7070  
**Qty Received:** 1 x Bottle

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	89 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM02

### Comments

Test carried out according to current Pharmacopoeias.

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

Date: 27 Nov 2015 16:48:51

Mrs P. Pham-Lengoc  
Laboratory Manager - Pharmaceutical Microbiology



# Wickham Laboratories

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

**Date Received:** 26 Nov 2015  
**Date Tested:** 01 Dec 2015  
**Date Test Completed:** 15 Dec 2015  
**Purchase Order:** 25557

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0026049/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 26/11/2015  
**Test Article:** ClearKlens IPA  
**Sample Code:** FMP15295 39094  
**Batch Ref:** 7070  
**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
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 Dec 2015 14:48:06

Mrs C Moore  
Laboratory Manager - Pharmaceutical Microbiology