



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 05.03.2012

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	0031485
Production Date	02/2012
Expiration Date	02/2014

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	0.877

On behalf of Diversey site Quality Manager	Name :	Mature
	Position	Quality Control Inspector

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

COA 7513400	Version : 03	Date of issuing : November 28 <sup>th</sup> 2011
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# CERTIFICATE OF IRRADIATION

Number: **B**

0521995 00

FLE001

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Flexible Medical Packaging Ltd  
Unit 8  
White Cross Industrial Estate  
Hightown  
Lancaster



## Synergy Health plc

Roydsdale Way · Euroway Trading Estate  
Bradford · West Yorkshire  
BD4 6SE · United Kingdom  
Telephone: +44 (0)1274 686011  
Facsimile: +44 (0)1274 686061  
Email: [assistance@synergyhealthplc.com](mailto:assistance@synergyhealthplc.com)  
Website: [www.synergyhealthplc.com](http://www.synergyhealthplc.com)

LA1 4XS

Cust. Ref: P018220  
Date Rec'd 23/02/12  
Date: 27/02/12

ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212020846	JD IPA BOTTLES 25-45kGy	354	B/No.W031485  ROUTINE DOSE 35.5, 35.8, 39.1 kGy's
B2FLE0010999 B212020846	SAMPLES	5	  CUSTOMER BATCH/CODE No.s AS ORDER No.P018220 DATED 22/2/12
Despatch Text:  7PLTS			
Total		359	Last Page 1 of 1

All in accordance with current  
Technical Agreement

This is to certify that the above items have been irradiated as  
specified above

Authorising Signature: *T. Coffey*

For and on behalf of SYNERGY HEALTH PLC



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

**Date Received:** 05 Mar 2012  
**Date Tested:** 07 Mar 2012  
**Date Test Completed:** 21 Mar 2012  
**Purchase Order:** 18274

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0003806/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 05/03/2012  
**Test Article:** Clearklens IPA Block 1  
**Sample Code:** 3200  
**Batch Ref:** WO31485  
**Qty Received:** 20 x 900mLs + 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

Test carried out according to current Pharmacopoeias.

*E. Langer*

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

*K.A. Barker*

Date: 22 Mar 2012 15:02:07

Mr K.A. Barker, CBIOL, MSB  
Business Manager - Microbiology

Consignment: 0003806

Certificate of Analysis - OSMM

Print Number: P0002147

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

**Date Received:** 05 Mar 2012  
**Date Tested:** 06 Mar 2012  
**Date Test Completed:** 06 Mar 2012  
**Purchase Order:** 18274

## CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0003806/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 05/03/2012  
**Test Article:** Clearklens IPA Block 1  
**Sample Code:** 3200  
**Batch Ref:** Works No. 31485  
**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
Product Standard Data Sheet	FG047/psd	FM02

### Comments

Test carried out according to current Pharmacopoeias.

*E. Gargan*

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

Date: 07 Mar 2012 11:23:23

Mrs P. Pham-Lengoc, BSc, MSB  
Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0003806

Certificate of Analysis - OSMM

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