



Diversey Europe BV

Maarssebroeksedijk 2  
3542 DN Utrecht  
The Netherlands

Tel. +31 (0)30 247 6427

## CERTIFICATE OF ANALYSIS

Date: 1/10/12

Product Name	CLEARKLENS IPA VH1
Product Code	7514372
Batch Number	EMP12258 32589
Production Date	09/2012
Expiration Date	09/2014

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 :	
	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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# CERTIFICATE OF IRRADIATION

Number: **B**  
Page 1

0547110 00

FLE001

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

LA1 4XS  
P019177  
Cust. Ref: 20/09/12  
Date Rec'd 27/09/12  
Date:



## 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  
Website: www.synergyhealthplc.com

ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212090680	JD IPA BOTTLES 25-45kGy	710	B/NO: W032589 - PROD REF: 7514372 FMP 12258-32589. (E4) 23/10/12 ROUTINE DOSE 38.6, 39.6, 40.7, 40.8 kGy
B2FLE0010999 B212090680	SAMPLES	6	CUSTOMERS BATCH/CODE NO'S AS ORDER P019177 DATED 20.09.12
Despatch Text:  14PLTS			
Total		716	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:

For and on behalf of SYNERGY HEALTH PLC



**Wickham Laboratories**  
contract analytical services

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

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

**Date Received:** 01 Oct 2012  
**Date Tested:** 02 Oct 2012  
**Date Test Completed:** 02 Oct 2012  
**Purchase Order:** PO19215

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0006932/2  
**Test Required:** Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP  
**Date Received:** 01/10/2012  
**Test Article:** Clearklens IPA Block 2  
**Sample Code:**  
**Batch Ref:** FMP12258 32589  
**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	113 %
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 is shown below.

Date: 03 Oct 2012 13:08:08

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

Consignment: 0006932

Certificate of Analysis - OSMM

Print Number: P0005838

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contract analytical services

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

**Date Received:** 01 Oct 2012  
**Date Tested:** 03 Oct 2012  
**Date Test Completed:** 17 Oct 2012  
**Purchase Order:** PO19215

### CERTIFICATE OF ANALYSIS

**Laboratory Reference Number:** 0006932/1  
**Test Required:** Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP  
**Date Received:** 01/10/2012  
**Test Article:** Clearklens IPA Block 2  
**Sample Code:** 3788  
**Batch Ref:** FMP12258, 32589  
**Qty Received:** 20 x 900mL Bottles + 4 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

6 bottles leaking out of total  
Test carried out according to current Pharmacopoeias.

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

Date: 18 Oct 2012 15:08:32

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

Consignment: 0006932

Certificate of Analysis - OSMM

Print Number: P0006167

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