

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

# **CERTIFICATE OF ANALYSIS**

Date: 20/4/12

Product Name	CLEARKLENS IPA VH1		
Product Code	7513400		
Batch Number	W03/8/0		
Production Date	04/2012		
Expiration Date	04/2014		

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 Lower - Upper	Results
Appearance	Visual	Clear Colourless Liquid	Clear Colowele
Specific Gravity (20°C)	JDM004	0.872 0.883	0.877

O 1 1 10 CD'	Name:	choscoe
On behalf of Diversey site  Quality Manager	Position	Quality Control Inspector

This document being issued electronical	ly does not bear a signature	
COA 7513400	Version: 03	Date of issuing : November 28th 2011

# CERTIFICATE OF IRRADIATION Number: B

Page

0527219 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref: 5/04/12 Date Rec'd 13/04/12 Date:

P018403

Synergy Health plc

Roydsdale Way · Euroway Trading Estate

1

Bradford · West Yorkshire BD4 6SE · United Kingdom Telephone: +44 (0)1274 686011 Facsimile: +44 (0)1274 686061

assistance@synergyhealthplc.com

Website: www.synergyhealthplc.com

Jale.			
ITEM CODE YNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212040243	JD IPA BOTTLES 25-45kGy	175	B/No.W031810
to the delivery of the second			ROUTINE DOSE 36.9, 37.0, 37.5 kGy
B2FLE0010999 B212040243	SAMPLES	6	
	-		CUSTOMER BATCH/CODE No.s AS ORDER No.P018403 DATED 4/4/12
		ti.	
40			
	Despatch Text:		
	4PLTS		
	Total	181	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: 7. Coffey.



Wickham Laboratories Limited Winchester Road, Wickham, Fareham Hampshire PO17 5EU England Telephone: +44 (0)1329 832511 Fax: +44 (0)1329 834262

mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster

LA14XS

Date Received:

24 Apr 2012

**Date Tested:** 

26 Apr 2012

**Date Test Completed:** 

26 Apr 2012

**Purchase Order:** 

18470

### **CERTIFICATE OF ANALYSIS**

**Laboratory Reference Number:** 

0004406/4

Test Required: **Date Received:**  Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

24/04/2012

**Test Article:** 

Clearklens IPA Block1

Sample Code:

WO31810

**Batch Ref: 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	63 %
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: 27 Apr 2012 11:45:42

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0004406

Certificate of Analysis - OSMM

Print Number: P0002709

Page 1 of 1



Wickham Laboratories Limited Winchester Road, Wickham, Fareham Hampshire PO17 5EU England Telephone: +44 (0)1329 832511

24 Apr 2012

02 May 2012

16 May 2012

18470

Fax: +44 (0)1329 834262 mail@wickhamlabs.co.uk www.wickhamlabs.co.uk

Date Received:

**Purchase Order:** 

**Date Test Completed:** 

Date Tested:

Mr J Jackson

Flexible Medical Packaging Limited

Unit 8

Hightown

Lancaster LA1 4XS

White Cross Industrial Estate

**CERTIFICATE OF ANALYSIS** 

**Laboratory Reference Number:** 

**Test Required:** 

Sterility Test by Membrane Filtration (Steritest) Method I: Ph Eur and USP

Date Received:

24/04/2012

Test Article:

Clearklens IPA Block 1

Sample Code:

Batch Ref:

WO31810

**Qty Received:** 

20 x 900mL + 3 Spores

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 50mL mL
Product Standard Data Sheet	FG047/psd	FM03
Commonto		

### **Comments**

Test carried out according to current Pharmacopoeias.

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

Ehr Lload

Date: 24 May 2012 14:38:07

Mrs S.L. Wood, BSc (Hons), CBiol, MSB

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0004863

Certificate of Analysis - OSMM

Print Number: P0003131

Page 1 of 1