

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 11.06.12

Product Name	CLEARKLENS IPA VH1 7514372		
Product Code			
Batch Number	FMP12138 WO32135		
Production Date	05/2012		
Expiration Date	05/2014		

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		clear wicher's
		Lic	quid	Liquid
Specific Gravity (20°C)	JDM004	0.872	0.883	0.877

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

This document being issued electronically does not bear a signature

COA 7514372 Version: 03 Date of issuing: November 28th 2011

CERTIFICATE OF IRRADIATION

Number: B

Page

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FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster string Estate
Synergyhealth
our work protects your world

LA1 4XS

Cust. Ref: Date Rec'd P018623 24/05/12 31/05/12

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.con

Website: www.synergyhealthplc.com

Date: 31/05/	12		
ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212050865	JD IPA BOTTLES 25-45kGy	709	B/No.W032135 - P/REF. 7514372 ROUTINE DOSE 37.3, 37.3, 36.7, 38.0 kGy's
B2FLE0010999 B212050865	SAMPLES	5	CUSTOMER BATCH/CODE No.s AS ORDER No.P018623 DATED 23/5/12
	Despatch Text:		
	Total	714	Last Page 1 of 1
		All in acco	rdance with current

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 Limited, Hoeford Point, Barwell Lane, Gosport Hampshire PO13 OAU England

Telephone: +44(0)1329 226600 +44(0)1329 832511

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+44(0)1329 226688

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:

06 Jun 2012

Date Tested:

11 Jun 2012

Date Test Completed:

11 Jun 2012

Purchase Order:

PO18665

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0005063/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Date Received:

06/06/2012

Test Article:

Clearklens IPA Block 2

Sample Code:

3523

Batch Ref:

WO32135

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	88 %
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: 13 Jun 2012 08:28:04

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0005063

Certificate of Analysis - OSMM

Print Number: P0003485

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received:

06 Jun 2012

Date Tested:

11 Jun 2012

Date Test Completed:

25 Jun 2012

Purchase Order:

P018665

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0005063/1

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

06/06/2012

Test Article:

Clearklens IPA Block 2

Sample Code:

3523

WO32135

Batch Ref: Qty Received:

20 x 900mL Bottles

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

See Investigation Report PHM 2012 090

Test carried out according to current Pharmacopoeias.

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

Date: 29 Jun 2012 15:00:53

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0005063

Certificate of Analysis - OSMM

Print Number: P0003809

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