

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 28/5/12

Product Name	CLEARKLENS IPA VH1		
Product Code	7513400		
Batch Number	WD 32134		
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		CLEUT CONOUTIESS
		Lic	quid	1,8010
Specific Gravity (20°C)	JDM004	0.872	0.883	0.877

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

This document being issued electronically does not bear a signature

COA 7513400 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

LA1 4XS P018609

Cust. Ref: Date Rec'd Date:

22/05/12 24/05/12 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

Email: assistance@synergyhealthplc.com Website: www.synergyhealthplc.com

Date: 247 037	1.4		
ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081	JD IPA BOTTLES 25-45kGy	709	B/No.W032134
B212050761			ROUTINE DOSE 37.3, 38.9, 37.1, 36.9 kGy
B2FLE0010999 B212050761	SAMPLES	5	
			CUSTOMER BATCH/CODE No.s AS ORDER No.P018609 DATED 21/5/12
	Despatch Text:		
	14PLTS		
	Total	714	Last Page 1 of 1
		All in acco Technical A	ordance with current 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

Fax:

+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 4X\$ Date Received:

28 May 2012

Date Tested:

31 May 2012

Date Test Completed:

31 May 2012

Purchase Order:

18635

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0004950/1

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Date Received:

28/05/2012

Test Article:

Clearklens IPA Block 1

Sample Code:

-

Batch Ref: Qty Received: WO32134

Test	Method Item	Result
Bacterial Endotoxin by Kinetic QCL Test	MM110/00	<0.2 EU/mL
Spiked Recovery	MM110/01	99 %
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.

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Date: 06 Jun 2012 12:44:05

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0004950

Certificate of Analysis - OSMM

Print Number: P0003348

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster

LA1 4XS

Date Received:

28 May 2012

Date Tested:

12 Jun 2012

Date Test Completed:

26 Jun 2012

Purchase Order:

18635

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0004949/1

Test Required:

Sterillty Test by Membrane Filtration (Steritest)

Date Received:

28/05/2012

Test Article:

Clearklens IPA Block 1

Sample Code:

-

Baich Ref: Qty Received: WO32134

20 x 900mL

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	11 x 50mL
Product Standard Data Sheet	FG047/psd	FM03
Comments		

Comments

See Deviation Report PHM 2012 080, Investigation report PHM2012 090

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

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Date: 28 Jun 2012 13:01:20

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0004949

Certificate of Analysis - OSMM

Print Number: P0003783

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