

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 14/8/12

Product Name	CLEARKLENS IPA VH1
Product Code	7513400
Batch Number	FMP12206 32487
Production Date	07/2012
Expiration Date	07/2014

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 Clar Colocille
Appearance	Visual	Clear Colourless Liquid	
Specific Gravity (20°C)	JDM004	0.872 0.883	0.877

On habelf of Director	Name:	CHASIR
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued el	ectronically does not bear a signature	
COA 7513400	Version: 03	Date of issuing: November 28th 2011
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CERTIFICATE OF IRRADIATION Number: B

0541476 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS P018919

Cust. Ref: Date Rec'd 2/08/12 6/08/12 Data

Page

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

Date: 6/08	/12		₹ ₹
ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212080117	JD IPA BOTTLES 25-45kGy	712	B/No.W032487 FMP 12206, DOLDENIS ROUTINE DOSE 38.7, 37.4, 37.8, 38.9 kGy
B2FLE0010999 B212080117	SAMPLES	5	CUSTOVED DATE
			CUSTOMER BATCH/CODE No.s AS ORDER No.P018919 DATED 1/8/12
,			
	Despatch Text:		
	14PLTS		
	Total	717	Last Page 1 of 1
		A11 :	

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

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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 LAI 4XS

Date Received:

13 Aug 2012

Date Tested:

15 Aug 2012

Date Test Completed:

15 Aug 2012

Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0006170/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

13/08/2012

Date Received: Test Article:

Clearklens IPA Block 1

Sample Code:

3652

Batch Ref:

FMP 12206 32487 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	101 %
Dilution Tested	MM110/04	1/40
Endotoxin Spike Level	MM110/02	0.5 EU/mL
Product Standard Data Sheet	FG047/psd	FM02

Comments

2 Boxes received on the 13/08/12, and 2 boxes received on the 14/08/12 Test carried out according to current Pharmacopoeias.

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

Shore Llucid

Date: 16 Aug 2012 12:29:56

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

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment; 0006170

Certificate of Analysis - OSMM

Print Number: P0004727

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS Date Received:

14 Aug 2012

Date Tested:

16 Aug 2012

Date Test Completed:

30 Aug 2012

Purchase Order:

P018977

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0006170/1

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

14/08/2012

Test Article:

Clearklens IPA Block 1

Sample Code:

3652

Batch Ref:

FMP 12206 32487

Qty Received:

20 x 900mL Bottles + 3 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

2 Boxes received on the 13/08/12, and 2 boxes received on the 14/08/12 Test carried out according to current Pharmacopoeias.

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

14x

Date: 03 Sep 2012 09:35:48

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0006170

Certificate of Analysis - OSMM

Print Number: P0005149

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