

Diversey Europe BV

Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427

CERTIFICATE OF ANALYSIS

Date: 7/2/12

Product Name	CLEARKLENS IPA VH1	
Product Code	7513400	
Batch Number	WC2 317.96	
Production Date	01/2012	
Expiration Date	01/2014	

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 -	e ppe	
Appearance	Visual	Clear Colourless		CHECKCOTOURIES
		Lic	quid	1190 d
Specific Gravity (20°C)	JDM004	0.872	0.883	0.877
			200 - 200 -	

On behalf of Diversey site Quality Manager	Name :	CHO300
	Position	Quality Control Inspector

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

CERTIFICATE OF IRRADIATION Number: B

0518541 00

FLE001

Flexible Medical Packaging Ltd

Unit 8

White Cross Industrial Estate

Hightown Lancaster

LA1 4XS

Cust. Ref:

P018067 26/01/12

Date Rec'd Date:

31/01/12

Page

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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: 017 017	*E		
ITEM CODE SYNERGY HEALTH BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
B2FLE0010081 B212010703	JD IPA BOTTLES 25-45kGy	720	B/No.W031296
			ROUTINE DOSE 36.8, 36.7, 37.8, 40.0 kGy
?FLE0010999 B212010703	SAMPLES	5	
			CUSTOMER BATCH/CODE No.s AS ORDER No.P018062 DATED 25/1/12
	Despatch Text:		
	14PLTS		
	Total	725	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 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:

06 Feb 2012

Date Tested:

07 Feb 2012

Date Test Completed:

07 Feb 2012

Purchase Order:

18112

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0003487/2

Test Required:

Bacterial Endotoxin Testing by Kinetic QCL: Ph Eur and USP

Date Received:

06/02/2012

Test Article: Sample Code: ClearKlens IPA Block 1

Work Order 31296 3061

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	143 %	
Dilution Tested	MM110/04	1/40	
Endotoxin Spike Level	MM110/02	0.5 EU/mL	
Product Standard Data Sheet	FG047/psd	FM02	

Comments

Corrected Certificate of Analysis to LR0003487/2 authorised 08 Feb 2012 14:30:05; typing error on Spiked Recovery. Test carried out according to current Pharmacopoeias.

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

Enr Llow.

Date: 11 May 2012 08:50:47

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

Senior Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0003487

Certificate of Analysis - OSMM

Print Number: P0002915

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Mr J Jackson

Flexible Medical Packaging Limited

Unit 8 Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

Date Received:

06 Feb 2012

Date Tested:

09 Feb 2012

Date Test Completed:

23 Feb 2012

Purchase Order:

18112

CERTIFICATE OF ANALYSIS

Laboratory Reference Number:

0003487/1

Test Required:

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

Date Received:

06/02/2012

Test Article:

ClearKlens IPA Block 1

Sample Code:

Work Order 31296 WO31296

Batch Ref: Qty Received:

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	20 x 50 mL
Product Standard Data Sheet	FG047/psd	FM03
Camanania		

Comments

Test carried out according to current Pharmacopoeias.

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

Date: 29 Feb 2012 10:34:16

Mrs P. Pham-Lengoc, BSc, MSB

Laboratory Manager - Pharmaceutical Microbiology

Consignment: 0003487

Certificate of Analysis - OSMM

Print Number: P0001804

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